

Exhibit B

Mareeni Stanislaus, M.D.

1 UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4
5 IN RE: ETHICON, INC. PELVIC Master File No.
6 REPAIR SYSTEM PRODUCTS 2:12-MD-02327
7 LIABILITY LITIGATION MDL No. 2327
8 _____ JOSEPH R. GOODWIN
9 THIS DOCUMENT RELATES TO: U.S. DISTRICT JUDGE
10 All TVT-O Cases
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16 VIDEOTAPED DEPOSITION OF EXPERT WITNESS

17 MAREENI STANISLAUS, M.D.

18 Paso Robles, California

19 Friday, July 15, 2016
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22
23

24 Reported by: Ashala Tylor, CSR No. 2436, CLR, CRR, RPR

25 Job #136049

Mareeni Stanislaus, M.D.

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3 Exhibit 14 Document entitled "41st Annual 142

Meeting-Cape Town, South Africa

4 August 4 - 5, 2016," no Bates

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6

7 INFORMATION REQUESTED

8 (None)

9 QUESTIONS NOT ANSWERED

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13 The videotaped deposition of MAREENI STANISLAUS,
14 M.D., the expert witness, was taken at Courtyard Paso
15 Robles, 120 South Vine Street, Paso Robles, California,
16 on Friday, July 15, 2016, at 1:04 p.m., before Ashala
17 Tylor, CSR No. 2436, Certified Shorthand Reporter in and
18 for the State of California, RPR, CRR, CLR.
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Mareeni Stanislaus, M.D.

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A P P E A R N C E S

FOR THE PLAINTIFFS:

WEXLER WALLACE LLP
BY: TIM E. JACKSON, ESQ.
55 West Monroe Street, Suite 3300
Chicago, Illinois 60603
312.346.2222
tej@wexlerwallace.com

FOR DEFENDANTS:

BOWMAN AND BROOKE LLP
BY: BARRY J. KOOPMANN, ESQ.
150 South Fifth Street, Suite 3000
Minneapolis, Minnesota 55402
612.339.8682
barry.koopmann@bowmanandbrooke.com

Also Present: Michael Brewer, Videographer

1 Friday, July 15, 2016; 1:04 p.m.

2 Paso Robles, California

3

4 THE VIDEOGRAPHER: Good afternoon. We are on
5 the record. My name is Michael Brewer. I'm a
6 videographer for Golkow Technologies.

7 Today's date is July 15th, 2016, and the time
8 is 1:04 p.m.

9 This video deposition is being held in
10 Paso Robles, California in the matter of Ethicon,
11 Incorporated Pelvic Repair System Products Liability
12 Litigation for the United States District Court,
13 Southern District of West Virginia at Charleston. The
14 deponent is Dr. Mareeni Stanislaus.

15 At this time will counsel please identify
16 themselves and state whom they represent.

17 MR. JACKSON: Tim Jackson from Wexler Wallace
18 on behalf of the Plaintiffs.

19 MR. KOOPMANN: Barry Koopmann from Bowman and
20 Brooke on behalf of Ethicon and Johnson & Johnson.

21 THE VIDEOGRAPHER: Thank you. The court
22 reporter is Ashala Tylor and will now swear in the
23 witness.

24 ///

25 ///

Mareeni Stanislaus, M.D.

1 MAREENI STANISLAUS, M.D.,
2 having been first placed under oath,
3 was examined and testified as follows:

4 THE VIDEOGRAPHER: You may begin.

5

6 EXAMINATION

7 BY MR. JACKSON:

8 Q. Doctor, could you please state and spell your
9 name for the record?

10 A. Mareeni Stanislaus. I'm sorry. Mareeni
11 Therese Stanislaus, M.D.

12 Q. Could you please spell that for the record?

13 A. Yes. M-A-R-E-E-N-I, middle name
14 T-H-E-R-E-S-E, last name Stanislaus,
15 S-T-A-N-I-S-L-A-U-S.

16 Q. Okay. Thank you.

17 Doctor, I introduced myself to you before we
18 got on the record, but my name is Tim Jackson, and I'm
19 from a law firm called Wexler Wallace in Chicago. And
20 you're here today to give testimony about your TVT-O
21 report in this case; is that correct?

22 A. That is correct.

23 Q. Okay. And is there any reason you feel you
24 cannot testify fully and accurately today?

25 A. No.

1 Q. If I ask something and it's not clear what I'm
2 asking, I'd just ask that you let me know that and I'll
3 do my best to rephrase the question so you understand
4 it. Is that fair?

5 A. Certainly.

6 Q. Okay. And, conversely, if I ask a question
7 and you answer it, is it fair to assume that you
8 understood the question?

9 A. Yes.

10 Q. Okay. Have you ever had your deposition taken
11 before?

12 A. Yes.

13 Q. Okay. And how many times?

14 A. Approximately five.

15 Q. When was the most recent?

16 A. In relation to this case, two weeks ago.

17 Q. Okay. And was that for a plaintiff specific
18 report?

19 A. Yes.

20 Q. Okay. And were there any other times in
21 relation to this case or just that one?

22 A. Just that one.

23 Q. Okay.

24 A. There were three consecutive depositions that
25 day.

1 Q. Okay. So are you counting those three
2 separate depositions in your total of five?

3 A. Yes.

4 Q. Okay. So there were two other instances where
5 you had your deposition taken?

6 A. Yes.

7 Q. Okay. And what -- can you tell us what those
8 two other instances were?

9 A. They were in regards to malpractice
10 litigation.

11 Q. Okay. And were you a defendant in those
12 cases?

13 A. Yes.

14 Q. Okay. In both of them?

15 A. Yes.

16 Q. Okay. And can you tell us what the dates of
17 those two cases were?

18 A. They were subsequently dropped without
19 prejudice. 2002, I think, and perhaps 2007.

20 Q. Okay. Thank you.

21 And, Doctor, prior to this case, have you ever
22 been retained as an expert witness before?

23 A. No.

24 Q. Okay. Doctor, what did you do to prepare for
25 your deposition today?

1 A. I reviewed textbooks. I reviewed my reliance
2 materials. I reviewed some of the literature and
3 reviewed my report.

4 Q. Okay. And when you say you reviewed
5 textbooks, would those be books that are listed on your
6 reliance materials?

7 A. I believe so, yes.

8 Q. Okay.

9 A. And, I'm sorry, I also consulted with my
10 counsel.

11 Q. Okay. I'm sorry, Doctor. When you say your
12 counsel, do you mean counsel for Ethicon?

13 A. Counsel for Ethicon, yes.

14 Q. And, Doctor, can you give me your best guess
15 of about how many hours you spent just preparing for the
16 deposition today aside from writing the report?

17 A. Oh, four hours.

18 Q. And aside from counsel, did you speak to
19 anyone else in regards to the deposition today prior to
20 the deposition?

21 A. No.

22 Q. Doctor, before we got on the record -- strike
23 that.

24 Before we got on the record we premarked as
25 Exhibit 1 this. And can you please confirm that that is

1 a true and accurate copy of the report you provided in
2 this case.

3 (Exhibit 1 was marked for
4 identification and attached hereto.)

5 (Pause while witness peruses document.)

6 THE WITNESS: Yes.

7 BY MR. JACKSON:

8 Q. Doctor, we've premarked as Exhibit 2 what I'll
9 represent is the CV that was provided along with your
10 report.

11 (Exhibit 2 was marked for
12 identification and attached hereto.)

13 BY MR. JACKSON:

14 Q. Does that look like a reasonably accurate copy
15 of your CV?

16 A. Yes.

17 Q. Okay. And, Doctor, what's been marked as
18 Exhibit 3 is the Mareeni Stanislaus reliance list in
19 addition to materials referenced in reports that were
20 provided with your report in this case.

21 (Exhibit 3 was marked for
22 identification and attached hereto.)

23 BY MR. JACKSON:

24 Q. Does that look reasonably correct to you?
25 It's a very long document. I'm not asking you to look

1 at every page.

2 A. I'm reading it --

3 (Pause while witness peruses document.)

4 Q. Okay. Doctor, Exhibit 4 is the Notice of
5 Deposition for this case. Have you seen that document
6 before?

7 A. Yes, I have.

8 (Exhibit 4 was marked for
9 identification and attached hereto.)

10 BY MR. JACKSON:

11 Q. Okay. Doctor, that document asks you to bring
12 certain documents with you today. You have those
13 documents; is that correct?

14 A. Yes. I'm not sure that the correct documents
15 were requested because these documents seem to refer to
16 patient information, which I don't have, but I did bring
17 all documents that I have related to my general report.

18 Q. Okay. And, just generally, can you tell us
19 what you brought with you today?

20 A. My report, my reliance list, literature,
21 various articles.

22 Q. Okay. And, Doctor, I believe you have a
23 binder in front of you. Can you tell us what that
24 specific binder is?

25 A. That is my general report with the articles

1 cited in my report.

2 MR. JACKSON: Okay. And could we go ahead and
3 mark that binder as Exhibit 5.

4 (Exhibit 5 was marked for
5 identification and attached hereto.)

6 BY MR. JACKSON:

7 Q. Doctor, is it fair to say that -- I'm sorry.

8 Doctor, is it fair to say that all of the
9 footnotes from your report are contained in that binder?

10 A. Yes.

11 Q. Have you written or highlighted on any of the
12 documents in the binder or are they clean copies?

13 A. They're clean copies.

14 Q. Okay. And, Doctor, aside from the binder
15 we've marked as Exhibit 5, you also brought a number of
16 other binders with you today, correct?

17 A. Yes, I did.

18 Q. And do those represent the reliance materials
19 you have in this case?

20 A. Yes, they do.

21 Q. Okay. And would it be fair to say that the
22 other binders, aside from Exhibit 5, are the same as the
23 documents listed on Exhibit 3, the reliance list?

24 A. Yes. I'm not entirely sure if they're all in
25 there, but I think so.

1 Q. Okay. Is it fair to say there wouldn't be any
2 new documents in the binders that are not on the
3 reliance list?

4 A. Yes, that would be fair to say.

5 Q. And I think what I'd like to do, if we could,
6 is mark all the other binders, aside from Exhibit 5, as
7 Exhibit 6 collectively. And then when we're on a break,
8 I can look at those a little more carefully.

9 Doctor, did you also bring some thumb drives
10 with you today?

11 A. Yes, I did.

12 Q. Okay. And what's on those thumb drives?

13 A. The complete set of documents and articles
14 related to this case that I reviewed. They principally
15 are the same as what is in these binders.

16 MR. JACKSON: Could we mark the thumb drives
17 as Exhibit 7?

18 (Exhibit 7-A was marked for
19 identification and attached hereto.)

20 (Exhibit 7-B was marked for
21 identification and attached hereto.)

22 BY MR. JACKSON:

23 Q. Doctor, when were you first contacted about
24 providing a report in this case?

25 A. I don't remember the exact date, but I would

1 say sometime in the last eight, nine months.

2 Q. Sometimes in the last eight, nine months.

3 Could you be any more specific than that? I mean, was
4 it, you know, was it the spring of 2016?

5 A. It was probably the fall of 2015, yes.

6 MR. KOOPMANN: Just make sure that he gets to
7 finish his question before you start answering so the
8 court reporter can take everything down.

9 BY MR. JACKSON:

10 Q. So, Doctor, you were first contacted in the
11 fall of 2015, approximately, about providing a report in
12 this case; is that correct?

13 A. That is correct.

14 Q. And when did you begin working on that report?

15 A. In April of 2016.

16 Q. Doctor, when you say you started in April of
17 2016, what did you start working on in April of 2016?

18 A. I started reviewing some literature regarding
19 the TVT-O. Just refreshing my memory.

20 Q. Okay. So is it fair to say -- strike that.

21 Doctor, prior to April of 2016, had you
22 previously read literature on the TVT-O device?

23 A. Yes, I had.

24 Q. Okay. And, Doctor, when did you submit your
25 report in this case, approximately?

1 A. It was June -- sorry. This is July. Forgive
2 me. June -- I've forgotten the exact date, actually.

3 Q. Doctor, is it fair to say you submitted your
4 report sometime --

5 A. Yes, I --

6 Q. -- in June of 2016?

7 THE REPORTER: One at a time, please.

8 Q. June of 2016?

9 A. Agreed.

10 Q. Thank you. And, Doctor, at the time you
11 submitted your report in this case, do you know how much
12 time you'd spent preparing that report?

13 A. Approximately 30 hours.

14 Q. Doctor, have you submitted an invoice for your
15 time in this case?

16 A. Yes, I have.

17 Q. And is that information you brought with you
18 today?

19 A. It was previously provided in the prior
20 deposition.

21 MR. KOOPMANN: Mr. Jackson, just for the
22 record, I think it was in the Hoke deposition.

23 MR. JACKSON: Thank you, Counsel.

24 Q. Doctor, what is your hourly rate for expert
25 work in this case?

1 A. \$400 an hour.

2 Q. And is that for any work you do in this case?

3 A. Yes.

4 Q. And, Doctor, we have a copy of your CV, so I
5 won't spend an inordinate time on that issue.

6 Could you tell us when where you went to
7 medical school?

8 A. I went to medical school at the University of
9 California, San Diego.

10 Q. Okay. And, Doctor, where did you do your
11 undergrad?

12 A. At Stanford.

13 Q. Okay. And you did a residency after medical
14 school?

15 A. I did.

16 Q. Where was that?

17 A. My residency was at the Hospital of the
18 University of Pennsylvania.

19 Q. And, Doctor, did you do a fellowship?

20 A. I did not.

21 Q. Doctor, what professional training do you have
22 post-residency?

23 A. Just my residency. And ongoing continuing
24 medical education courses.

25 Q. And, Doctor, when did you complete your

1 residency?

2 A. In 1996, July.

3 Q. And, Doctor, you mentioned continuing medical
4 education. Is that the phrase you used?

5 A. Yes.

6 Q. What do you mean by that term?

7 A. Attending courses sponsored by the various
8 organizations relevant to my specialty; reading
9 materials; maintaining my board certification.

10 Q. Doctor, what board certification do you hold?

11 A. The American Board of Obstetrics In
12 Gynecology.

13 Q. So, Doctor, you are board certified in
14 obstetric -- obstetrics and gynecology; is that correct?

15 A. That is correct.

16 Q. Okay. And, Doctor, is that certification done
17 on a state level or is it on the national level?

18 A. The national level.

19 Q. And, Doctor, does the American Board of
20 Obstetrics and Gynecology offer a board certification in
21 female pelvic health and reconstructive surgery?

22 A. They did not at the time that I graduated
23 residency, but they do now.

24 Q. Okay. They do now.

25 A. Uh-huh.

1 Q. And when did they begin offering that board
2 certification?

3 A. I'm not aware of the exact date. My
4 recollection is sometime around 2006, maybe.

5 Q. Okay. That's something you have not pursued,
6 though?

7 A. No, I have not.

8 Q. Okay. Is it something you could pursue?

9 A. At this point it would be very difficult for
10 me to pursue that. No, so...

11 Q. Okay. Doctor, what does a board certification
12 in female pelvic health and reconstructive surgery
13 entail?

14 MR. KOOPMANN: Object to the form.

15 THE WITNESS: To be honest, I haven't reviewed
16 the exact requirements. My understanding is that it
17 requires devoting greater than 50 percent of your
18 practice to female pelvic medicine and completing
19 fellowship training. I don't remember if that training
20 requires two or three years post-residency.

21 BY MR. JACKSON:

22 Q. Doctor, would it be fair to say that a
23 physician who had a board certification in female pelvic
24 health and reconstructive surgery has training and
25 education above and beyond what you, yourself, have?

1 A. That would not be fair to say.

2 Q. And why not?

3 A. It is a new specialty. And at the time that I
4 completed my training I had the same training and,
5 perhaps, more experience, than many of the current
6 trainees in female pelvic medicine and reconstructive
7 surgery.

8 Q. Okay. Doctor, you completed your residency
9 20 years ago?

10 A. Correct.

11 Q. Okay. And, Doctor, in that 20 years you could
12 have obtained a board certification in female pelvic
13 health and reconstructive surgery?

14 MR. KOOPMANN: Object to form.

15 (Reporter clarification.)

16 MR. KOOPMANN: Object to form.

17 THE WITNESS: That is not something that I
18 would have required to practice my specialty. But the
19 specific answer is, I suppose I could have.

20 BY MR. KOOPMANN:

21 Q. Doctor, do you know how many -- I'm sorry.
22 Strike that.

23 Do you know about how many physicians in the
24 United States are board certified in female pelvic
25 health and reconstructive surgery?

1 A. I do not.

2 Q. Do you have a sense of if it's more or less
3 than a thousand?

4 A. My sense is that it's less than a thousand.

5 Q. Doctor, do you consider yourself an expert in
6 female pelvic medicine and reconstructive surgery?

7 A. I certainly do.

8 Q. Doctor, have you performed research in your
9 medical career regarding treatments for stress urinary
10 incontinence?

11 A. I have not.

12 Q. Doctor, have you performed any research in
13 your career regarding polypropylene mesh for the
14 treatment of stress urinary incontinence?

15 A. I have not published research. I have
16 examined my own outcomes.

17 Q. Doctor, when you say you examined your own
18 outcomes, can you explain what you mean by that?

19 A. I take care of my patients. I follow them
20 intraoperatively and postoperatively to see how they're
21 doing.

22 Q. Okay. Doctor, have you authored any
23 publications in your medical career?

24 A. No, I have not.

25 Q. Doctor, have you ever served on a peer review

1 board for a medical journal?

2 A. No, I have not.

3 Q. Doctor, have you ever directed a clinical
4 study regarding treatments for stress urinary
5 incontinence?

6 A. No.

7 Q. Doctor, have you ever directed any clinical
8 study regarding polypropylene mesh in any application?

9 A. No.

10 Q. Doctor, have you ever directed a clinical
11 study of any kind?

12 A. Not as a principal director, no.

13 Q. Other than as a principal director, have you
14 ever directed a clinical trial?

15 A. I'm presently involved in facilitating some
16 clinical trials for a postpartum hemorrhage device.

17 Q. Doctor, do you currently implant the TVT
18 obturator device?

19 A. I do.

20 Q. And, Doctor, when did you last implant a TVT
21 obturator device in a patient?

22 A. I don't remember the exact date. It's been
23 about six years.

24 Q. So, Doctor, just so we're clear, when you say
25 you do currently implant the TVT obturator product but

1 you haven't implanted one in six years, can you just
2 reconcile what that means?

3 A. That means that I consider the TVT obturator
4 device in armamentarium of devices to be used for stress
5 incontinence. In recent times, I have been preferring
6 to use a mini sling device, but in the appropriate
7 patients I would still use a TVT obturator.

8 Q. When you say "the appropriate patients," can
9 you tell me what you mean by that?

10 A. So I counsel my patients as to the
11 risks/benefits of any incontinence procedure. I present
12 the potential morbidity to them and help them come to a
13 decision as to which procedure to perform. Recently my
14 patients have been choosing to have the mini sling.

15 Q. And, Doctor, when you say morbidity, what does
16 that mean?

17 A. That means pain after surgery. That means
18 recovery, loss of time from work, potential
19 intraoperative complications, needing to -- well,
20 voiding problems, things I discuss with any surgical
21 patient, uh-huh.

22 Q. And so, Doctor, is it fair to say that
23 different -- different sling devices for the treatments
24 of stress urinary incontinence have different
25 morbidities associated with them?

1 A. Different sling devices, that's a broad term.
2 But, yes, because of pubovaginal slings have different
3 morbidity than polypropylene, yes, that's true,
4 uh-huh.

5 Q. I didn't ask a very good question. Let me ask
6 a better one.

7 Doctor, does the TVT retropubic device have a
8 different morbidity associated with it than the TVT
9 obturator device?

10 A. Yes, slightly.

11 Q. When you say "slightly," what do you mean by
12 that?

13 A. I think their overall morbidity is about the
14 same, but the particular location of, say, postoperative
15 pain might be slightly different that with the two
16 techniques.

17 Q. Doctor, when you say their overall morbidities
18 are approximately the same, what's your basis for that
19 statement?

20 A. That would be the -- review the literature,
21 multi-center randomized trials.

22 Q. Doctor, have you reviewed some literature as
23 part of your work in this case that points out different
24 complications associated with the TVT retropubic device
25 versus the TVT obturator device?

1 A. Yes.

2 Q. When you say the TVT retropubic device and the
3 TVT obturator device have approximately the same
4 morbidities associated with them, what does
5 "approximately" mean in that context?

6 A. Within a few percentage points either way.

7 Q. Doctor, are you aware of any published
8 literature where there have been statistically
9 significant differences in complication rates between
10 the TVT retropubic device and the TVT obturator device?

11 A. Yes.

12 Q. Do you find those studies relevant and
13 reliable?

14 MR. KOOPMANN: Object to form.

15 THE WITNESS: It's hard to comment on some
16 studies. I'd have to know which studies. But in
17 reference to my statement, I would say that there --
18 when reviewing any study, it's important to note the
19 statistical significance and also the potential clinical
20 significance because to a particular patient a
21 particular morbidity may be more relevant, so...

22 BY MR. JACKSON:

23 Q. Doctor, about how many TVT-O procedures have
24 you performed in your career?

25 A. Approximately 150.

1 Q. And when did you start using the TVT
2 obturator?

3 A. So I did not review my exact date of start,
4 but it was approximately 2004.

5 Q. And, Doctor, I think you said you stopped
6 using it about six years ago?

7 A. I have not stopped using it, but the last time
8 I used it was approximately six years ago.

9 Q. I apologize.
10 Doctor, is it fair to say that you implanted
11 150 TVT-O devices between 2004 and 2010?

12 A. Yes.

13 Q. And, Doctor, how did you come to use the TVT
14 obturator device initially?

15 A. I was introduced to it, I think, first by
16 reading some articles in the literature. And I went to
17 a training course sponsored by Ethicon to further
18 understand the anatomy of the device and practice on a
19 cadaver.

20 Q. So, Doctor, you read articles about the TVT
21 obturator device before using it in 2004; is that
22 correct?

23 A. I do not recall whether they were specific to
24 the TVT obturator device, but they were relevant to the
25 technique, yes.

1 Q. Doctor, when was the first time you had any
2 interaction with Ethicon?

3 A. Oh, I really can't remember. I must have had
4 some interaction when I was a resident in the, you know,
5 early '90s.

6 Q. Okay. Doctor, prior to implanting the TVT
7 obturator in 2004, did you also implant the TVT
8 retropubic device?

9 A. Yes, I did.

10 Q. And prior to implanting the TVT retropubic
11 device, are there any other Ethicon devices you
12 implanted before the TVT retropubic?

13 A. Before the TVT retropubic? Sorry. Ethicon
14 incontinence -- sorry, what was your question? Repeat
15 it again.

16 Q. Let me ask a better question.

17 Doctor, did you implant any Ethicon -- strike
18 that.

19 Doctor, did you use any Ethicon products for
20 any indication, not just stress urinary incontinence,
21 prior to using the TVT retropubic device?

22 A. Yes.

23 Q. And what devices would those be?

24 A. So that is difficult for me to answer because
25 I didn't always pay attention to who the manufacturer

1 was, but I suspect that I used some of the laparoscopic
2 equipment. And also -- sorry -- I'm sure I used their
3 suture.

4 Q. And, doctor, when you say "laparoscopic
5 equipment," that's not anything that's permanently
6 implanted, is it?

7 A. Laparoscopic equipment, they may have made a
8 stapler that that would be permanently implanted. The
9 staples remain.

10 Q. Okay. Doctor, when -- have you implanted both
11 mechanical cut and laser cut TVT obturator devices?

12 A. To the best of my knowledge, yes.

13 Q. Okay. Doctor, when you're doing a TVT
14 obturator surgery, do you know whether it's a
15 mechanically cut or a laser cut product?

16 A. I do know how to find out, but it's not
17 something that I specifically request one or the other.

18 Q. Doctor, if you were to hold a mechanically cut
19 TVT obturator mesh in one hand and a laser cut TVT
20 obturator mesh in the hand and just visually looked at
21 them, could you tell a difference?

22 A. Yes.

23 Q. And how could you tell a difference?

24 A. I haven't done this in some time, but I think
25 the edges are slightly different, the look to the edge.

1 Q. And can you be any more specific there?

2 A. Not particularly. They look quite similar.

3 Q. Okay. But you believe the edges might look a
4 little different?

5 A. Yes.

6 Q. Okay. And so, Doctor, other than the TVT
7 obturator device, do you currently implant any other
8 Ethicon devices for stress urinary incontinence?

9 A. Yes, the TVT-Exact.

10 Q. And when was the last time you implanted a
11 TVT-Exact?

12 A. Three months ago.

13 Q. And about how many TVT-Exacts have you
14 implanted in your career?

15 A. The actual Exact, not that many. Probably 20.

16 Q. Okay. And, Doctor, other than the obturator
17 and the exact, are there any other Ethicon devices that
18 you currently implant?

19 A. I have not used any lately, but, yes, the
20 Abbrevio. That's it.

21 Q. And, Doctor, when did you last implant an
22 Abbrevio?

23 A. Gosh, more than six years ago. Maybe eight
24 years ago.

25 Q. And about how many Abbrevos have you

1 implanted?

2 A. Four, five.

3 Q. Okay. Doctor, do you currently implant the
4 retropubic TVT device?

5 A. Yes.

6 Q. You do. Okay. And when did you last implant
7 a retropubic TVT device?

8 A. Forgive me. I may be misspeaking. I equate
9 the TVT-Exact with the retropubic TVT device. Are we
10 speaking of the same thing?

11 Q. No.

12 A. Okay.

13 Q. Doctor, are you aware that there was a
14 retropubic TVT device prior to the launch of the
15 TVT-Exact?

16 A. Yes, I am.

17 Q. Okay. And do you currently implant the
18 retropubic non-Exact TVT device?

19 A. No, I do not.

20 Q. You do not. Have you ever implanted the
21 retropubic non-Exact TVT device?

22 A. Yes, I have.

23 Q. And when did you last implant the retropubic
24 non-Exact TVT device?

25 A. Gosh, it would have been -- it's really quite

1 a guess. Probably 2005.

2 Q. Doctor, when was the first time you ever
3 worked with polypropylene mesh of any type?

4 A. I really don't remember the exact date. It
5 must have been sometime around 1997 or '8.

6 Q. And was that for an indication other than SUI
7 repair?

8 A. Yes.

9 Q. What would that have been for?

10 A. Abdominal sacral colpopexy.

11 Q. Doctor, have you performed Burch procedures
12 for stress urinary incontinence repair?

13 A. Yes, I have.

14 Q. And when did you last perform a Burch
15 procedure for stress urinary incontinence repair?

16 A. Approximately two years ago.

17 Q. Doctor, would you agree that the Burch
18 procedure is within the standard of care for treating
19 stress urinary incontinence?

20 A. Yes, it is within the standard of care.

21 Q. And, Doctor, how many Burch procedures have
22 you performed in your career?

23 A. Approximately 200.

24 Q. Doctor, have you attended any Ethicon
25 training?

1 A. Yes.

2 Q. Okay. And was that training specific to
3 stress urinary incontinence products?

4 A. Yes.

5 Q. Okay. And which products did you specifically
6 attend Ethicon training on?

7 A. I specifically attended training on the TVT
8 obturator. I attended training on Prolift. And I may
9 have also attended training on the TVT Secure. I can't
10 remember if that was at the same time as the Prolift or
11 not.

12 Q. And, Doctor, have you ever implanted the TVT
13 Secure?

14 A. Yes.

15 Q. You have. And when did you last implant a TVT
16 Secure?

17 A. It's been many years. Perhaps 2011.

18 Q. And, Doctor, the TVT obturator Ethicon
19 training you mentioned you attended, do you remember
20 approximately when that was?

21 A. No. It -- approximately 2004.

22 Q. And do you remember where you attended that
23 training?

24 A. I recall it was in Phoenix.

25 Q. And, Doctor, just can you describe what the

1 training entailed?

2 A. It entailed morning of lectures and videos,
3 and then I think the afternoon was a cadaver lab
4 implanting the device.

5 Q. And, Doctor, did you receive any sort of
6 certificate as a result of that training?

7 A. I would have. Yes, I did.

8 Q. Doctor, I'm going to turn to your report,
9 which I think we marked as Exhibit 1.

10 A. Okay.

11 Q. And, Doctor, if you'd like to refer to the
12 report you brought with you or Exhibit 1, whichever you
13 prefer.

14 A. Uh-huh.

15 Q. Doctor, I'm just going to start on page 5.
16 Could you let me know when you're on page 5 of your
17 report?

18 A. Yes, I'm on page 5.

19 Q. And I'm -- this is a section called Clinical
20 Experience & Personal Experience with SUI Treatments; is
21 that correct?

22 A. That is correct.

23 Q. And, Doctor, what clinical experience are you
24 describing on this page?

25 A. That's my care for patients.

1 Q. And, Doctor, I'm looking at a sentence, the
2 second sentence in the second paragraph. It says, "I
3 learned the procedures after residency, due to the
4 ever-growing body of literature which supported their
5 efficacy in the setting of marked improvement and return
6 to normal function."

7 Did I read that correctly?

8 A. Yes, you did.

9 Q. What do you mean by that sentence?

10 A. I mean that I chose to learn this technique
11 once I recognized through reading of the literature that
12 it was a technique that would provide great -- a great
13 boon to women in that they can return to work faster and
14 still have an effective procedure for their
15 incontinence.

16 Q. And, Doctor, you mentioned the literature in
17 this sentence.

18 A. Yes.

19 Q. And I'm just curious, can you just explain to
20 me what the ever-growing body of literature means in
21 that context?

22 A. At that time I typically read The Green
23 Journal and The Gray Journal, and some of the other
24 throw-away publications like Contemporary OB-GYN. And
25 as I saw more and more information regarding the sling

1 procedures, I recognized that this was something I
2 should learn to do.

3 Q. Okay. So, Doctor, just so I'm clear, you're
4 -- strike that.

5 Doctor, are you saying that you -- due to the
6 literature accumulating on the device, you were inspired
7 to go out and start performing the device yourself?

8 A. That is what I'm saying.

9 Q. Okay. And, Doctor, further down on page 5,
10 the first sentence of the last paragraph it says, "When
11 the TVT was first introduced, I waited until there was a
12 wealth of peer-reviewed data surrounding it before
13 adopting it into my practice, but I have been
14 overwhelmingly pleased with the results since I have
15 adopted it and other mid-urethral slings."

16 Did I read that correctly?

17 A. Yes, you did.

18 Q. And, Doctor, when you use the TVT in this
19 context, what are you referring to?

20 A. In this context, I'm referring to the
21 polypropylene mid-urethral sling.

22 Q. And when you say, "When the TVT was first
23 introduced," are you referring to a specific iteration
24 of the TVT or the entire family of TVT?

25 A. In this particular sentence I suppose I would

1 be referring to the first TVT, the retropubic.

2 Q. Okay. And that would be the non-Exact
3 retropubic?

4 A. Correct, yes.

5 Q. And, Doctor, you say you waited until there
6 was a wealth of peer-reviewed data surrounding it before
7 adopting it into your practice, correct?

8 A. Yes, I did.

9 Q. And so when did you adopt it into your
10 practice?

11 A. The -- approximately 2002.

12 Q. And, Doctor, when did the TVT retropubic --
13 I'm sorry, strike that.

14 Doctor, when was the retropubic TVT first
15 marketed in the United States?

16 A. I think it was in 1998.

17 Q. Okay. And, so, Doctor, do you believe that
18 prior to 2002 there was inadequate data surrounding the
19 TVT retropubic?

20 MR. KOOPMANN: Object to form.

21 THE WITNESS: There was excellent data prior
22 to 2002. I chose to be cautious and wait until it was
23 more widely accepted.

24 BY MR. JACKSON:

25 Q. Okay. Doctor, when you say there was

1 excellent data surrounding the TVT retropubic prior to
2 2002, is there any specific data you're referring to as
3 excellent?

4 A. Oh, well, I read the initial -- I think it was
5 an Omsten article.

6 Could you repeat your question? You were
7 saying prior to 2002?

8 Q. Let me back up, Doctor. You state here
9 that -- strike that.

10 Doctor, you waited until 2002 to start using
11 the TVT retropubic device, correct?

12 A. Correct.

13 Q. And you state in your report you waited until
14 there was a wealth of peer-reviewed data.

15 A. I did.

16 Q. Okay. And so do you believe that prior to
17 2002, there was a wealth of peer-reviewed data on the
18 TVT retropubic device?

19 A. I do believe there was a wealth of
20 peer-reviewed data prior to 2002, yes.

21 Q. So, Doctor, why did you wait until 2002 to
22 start using the TVT retropubic device?

23 A. Because I had wonderful success with my Burch
24 procedures. I didn't have a strong impetus to change.
25 But as I read the data and realized that women were

1 doing better, I thought I better look into this a little
2 further.

3 Q. Okay. So is it fair to say that you wanted to
4 be cautious before you started using it?

5 A. I typically am cautious, so, yes, it is fair
6 to say that. However, part of my delay in adopting it
7 was I didn't have a need to adopt it due to my good
8 outcomes with the Burch.

9 Q. Doctor, the next sentence on page 5 states, "I
10 routinely have patients approach me at the grocery store
11 and at social events with tears of gratitude in their
12 eyes for the improvement they have experienced and their
13 quality of life from the mesh sling procedure."

14 Did I read that correctly?

15 A. Yes, you did.

16 Q. And that must be very rewarding.

17 A. It is.

18 Q. And about how many times has that happened
19 where a patient approached you in a grocery store?

20 A. Oh, 50.

21 Q. And would those 50 patients who approached you
22 in a grocery store include multiple products that you've
23 implanted, not just the TVT obturator?

24 A. Yes, they would include multiple products.

25 Q. So, Doctor, the sentence that I just read from

1 page 5 that begins, "I routinely have patients," does
2 that refer just to the TVT obturator or does it refer to
3 multiple products?

4 A. It refers to polypropylene sling products
5 generally.

6 Q. Doctor, can you definitively say that any of
7 those instances involved TVT obturator products?

8 A. Yes, I can.

9 Q. And how can you be sure?

10 A. Well, during that particular time was when my
11 children were playing soccer, and I would see these moms
12 at the soccer field. And at the period of time I was
13 using the TVT-O, I was using it almost exclusively.

14 Q. And, Doctor, what -- during what time period
15 were you using the TVT-O almost exclusively?

16 A. About 2004 to about 2009.

17 Q. And, Doctor, do you recall the last time a
18 woman came up to you in the grocery store and shared a
19 positive experience with a TVT product with you?

20 A. With any TVT product, not specifically the
21 TVT-O?

22 Q. Correct.

23 A. Oh, about a month ago.

24 Q. And, Doctor, do you recall the last time a
25 woman came up to you in a grocery store and shared a

1 positive experience with a TVT obturator device?

2 A. I don't recall an exact date, no, or time.

3 Q. And, Doctor, are these encounters with
4 patients in the grocery store part of the information
5 you've considered in reaching your opinion that the TVT
6 obturator device is safe and effective?

7 A. It's part of it. It's not the principal
8 source of my information.

9 Q. But it's part of it?

10 A. It's part of it, yes, uh-huh.

11 Q. And, Doctor, do you intend to discuss at trial
12 any encounters you've had with patients in the grocery
13 store?

14 A. Only if it's asked of me. It's not the type
15 of information I typically volunteer.

16 Q. But do you believe those encounters are
17 relevant to your opinion that the TVT-O device is safe
18 and effective?

19 A. I suppose so, yes, uh-huh.

20 Q. And would you like to talk about those
21 encounters at trial if you were allowed?

22 A. Certainly. I don't know, really. As I said,
23 if asked, I will. If I could state one other thing,
24 it's not really relevant to whether I consider the TVT-O
25 is safe and effective. It's more relevant to the fact

1 that I consider it to have a low morbidity and high
2 patient acceptance.

3 Q. Okay. Thank you, Doctor.

4 Can you explain how safety and low morbidity
5 are different concepts? Because I think that's what you
6 said in your last answer.

7 A. Yeah. Well, safety would apply to
8 life-threatening or significantly life-altering events.
9 And effectiveness would apply to, you know, the -- how
10 well the device worked. In terms of morbidity, there
11 are other less tangible factors, such as how quickly one
12 can walk around a room, whether one can return to work,
13 whether there's, you know, a need to have a catheter
14 placed that might prohibit you from going to the grocery
15 store yourself, you know, things like that.

16 Q. Okay. So, Doctor, are you offering an opinion
17 in this case that the TVT-O device is safe and
18 effective?

19 A. Yes, I am.

20 Q. Okay. And, Doctor, are you offering any
21 opinions in this case regarding the morbidity associated
22 with the TVT obturator device?

23 A. Yes, I am.

24 Q. Okay. And, Doctor, how do you believe your
25 opinions about the morbidity of the TVT obturator device

1 and the safety of the TVT obturator device are
2 different?

3 A. Well, my opinion is that the TVT device is
4 safe and effective. My opinion is that the TVT-O has
5 low morbidity. So they're not terribly different.

6 Q. Okay.

7 A. But it's a bit like comparing apples and
8 oranges. It's hard for me to say they are exactly the
9 same opinion.

10 Q. Okay. Fair enough.

11 Doctor, if I could ask you to locate what we
12 marked as Exhibit 3, which is the list of -- the
13 reliance list.

14 Doctor, just generally, have you reviewed
15 every document on this list?

16 A. I have looked at every document on this list,
17 yes.

18 Q. Okay. And, Doctor, about how much time did it
19 take you to look at every document on this list?

20 A. A long time. Several days.

21 Q. Several days. When you say "several days," do
22 you mean --

23 A. I mean --

24 Q. -- consecutively or working a certain number
25 of hours a day?

1 A. Working a certain number of hours a day. I
2 would typically set aside one or two hours per day to do
3 so over the span of, perhaps, two weeks.

4 Q. So what would be your best guess of how many
5 hours you spent reviewing these?

6 A. My best guess is maybe 30 hours.

7 Q. 30 hours?

8 A. Uh-huh.

9 Q. Okay. And that's just reviewing the
10 materials?

11 A. Let's say 25 hours just reviewing materials.

12 Q. Okay. Doctor, do you have an active practice
13 right now?

14 A. I do, yes.

15 Q. Where do you currently work?

16 A. In Templeton, California at the Pacific
17 Central Coast Health Centers.

18 Q. And you work there as a
19 obstetrician/gynecologist, correct?

20 A. I do.

21 Q. And, Doctor, how long have you been in that
22 position?

23 A. Almost two years.

24 Q. And, Doctor, you said you reviewed all the
25 materials on this list, correct?

1 A. Correct.

2 Q. And is it fair to say you did not discuss all
3 the materials on the list in your report?

4 A. That is fair to say.

5 Q. Okay. So how did you go about choosing which
6 materials from this list would be discussed in your
7 report?

8 A. I wanted to rely on the highest quality of
9 evidence. So principally I chose from the systematic
10 reviews and meta-analyses.

11 Q. Doctor, would you consider any published
12 peer-reviewed literature that discusses the TVT
13 obturator device as relevant to your opinions in this
14 case?

15 A. Once again, it would depend on the quality of
16 the evidence.

17 Q. And, Doctor, you read some Ethicon internal
18 documents that were provided to you, I assume?

19 A. Yes, I did.

20 Q. Okay. And how did you determine which ones
21 you were going to list in your report? Strike that.

22 Doctor, there are a few Ethicon documents
23 listed as footnotes in your report, correct?

24 A. Yes.

25 Q. How did you decide which of those to include

1 in your report from the long list in your reliance
2 materials?

3 A. If I might take a moment. You're referring to
4 the Ethicon documents that I referenced?

5 Q. Correct.

6 A. It was just if it was relevant to my opinion,
7 it was just --

8 Q. Well, Doctor, I'll represent to you that there
9 are, we'll say, over 100 Ethicon documents on your
10 reliance list. And you --

11 A. True.

12 Q. -- only cited a very small fraction of that in
13 your report; is that fair?

14 A. That's fair.

15 Q. And how did you select just those very few?

16 MR. KOOPMANN: Object to the form.

17 THE WITNESS: I did not rely much on the
18 Ethicon company documents, to be honest, but there were
19 a few specific questions that I had addressed relating
20 to the type of material used. And the only information
21 that I could find relevant to that was in the Ethicon
22 company documents.

23 BY MR. JACKSON:

24 Q. Okay. Doctor, how did you become involved in
25 this case in the fall of 2015?

1 A. I was contacted by Mr. Koopmann.

2 Q. And at the time you were contacted by
3 Mr. Koopmann in the fall of 2015, did you believe that
4 the TVT-O device was safe and effective?

5 A. Yes, I did.

6 Q. And at the time you were first contacted by
7 Mr. Koopmann, did he explain that he wanted you to
8 provide a report stating that the TVT-O device was safe
9 and effective?

10 MR. KOOPMANN: I object to the form of the
11 question. I think that calls for communications between
12 myself and the witness which is privileged under the
13 rules. So I'm going to instruct the witness not to
14 answer.

15 BY MR. JACKSON:

16 Q. Okay. I can ask a better question. Doctor,
17 at the time -- strike that.

18 Doctor, is it fair to say that no matter --
19 Doctor, you said in the fall of 2015, when you were
20 first contacted in this case, you held the opinion that
21 the TVT-O device was safe and effective; is that
22 correct?

23 A. That is correct.

24 Q. And is it fair to say you didn't see or learn
25 anything that changed your mind?

1 A. Yes, that's fair to say. If I may elaborate.
2 Reviewing some of the more recent meta-analyses further
3 reinforced that opinion.

4 Q. So, Doctor, since you began work in this case,
5 have you done any research independently to determine
6 whether your initial view that the TVT-O device was safe
7 and effective was correct?

8 A. Yes, I looked up -- up to date, I reviewed the
9 recent physician statements by my professional
10 societies.

11 Q. Doctor, what professional societies are you a
12 member of?

13 A. American College of OB-GYN, the American
14 Urogynecologic Society.

15 Q. Doctor, is the American Urogynecologic Society
16 also known as AUGS?

17 A. Yes. AMA.

18 Q. Doctor, how did you go about deciding what
19 information to include in your report in this case?

20 A. I formulated my opinions. And I looked
21 through some of the documents provided to me. And I did
22 a literature search on my own, and looked to see what
23 seemed to reasonably support my -- the opinions that I
24 have stated.

25 Q. So is it fair to say you had your opinions

1 first and then you filled in the report with support for
2 those opinions?

3 MR. KOOPMANN: Object to form.

4 THE WITNESS: Having been in practice for
5 20 years and gone to medical school and residency as I
6 have had the opportunity to form some opinions, those
7 opinions would have been subject to change had I found
8 contrary information. But, yes, I did have some
9 opinions before I started the report.

10 BY MR. JACKSON:

11 Q. Doctor, you discussed the instructions for
12 use, or IFU, for the TVT obturator in your report,
13 correct?

14 A. Correct.

15 Q. How did you determine to discuss the TVT
16 obturator IFU in your report?

17 A. Well, it has been a subject of question, I
18 think, in prior litigation so I thought it might be
19 relevant.

20 Q. Okay. And, Doctor, you discuss the background
21 of the TVT retropubic and the TVT obturator in your
22 report --

23 A. Yes.

24 Q. -- correct?

25 And you also discuss literature surrounding

1 both those devices in your report?

2 A. Yes.

3 Q. Doctor, you discuss the IFU for the TVT
4 obturator in your report?

5 A. Yes.

6 Q. And, Doctor, you also discuss Ethicon's
7 training programs in your report?

8 A. Yes.

9 Q. And you discuss Ethicon's product brochures in
10 your report, correct?

11 A. Yes, uh-huh.

12 Q. Okay. And are there any other sections in
13 your report that I didn't just list?

14 A. Everything is listed here. There may be
15 something that you haven't mentioned.

16 Q. Okay. Well, how did you decide to include
17 those sections and not other sections?

18 A. Well, I had a general outline that I felt
19 would be relevant, and then additional material in
20 discussion with counsel to see what might be relevant.

21 Q. Okay. And how did you come up with that
22 initial general outline?

23 A. I asked counsel some questions. I asked some
24 of my colleagues what generally goes in a expert report.

25 Q. Okay.

1 A. Not relevant to this particular case, but...

2 Q. Okay. And, Doctor, if I can ask you to turn
3 back to Exhibit 3, the reliance list.

4 A. Uh-huh.

5 Q. And I took the liberty of tabbing a page to
6 streamline things. If I could ask you to turn to that
7 tabbed page.

8 A. Yes.

9 Q. I had a few questions about some of the things
10 on this page.

11 A. Okay.

12 Q. Doctor, do you see just about halfway down the
13 page it says, "FDA 24-Hour Summary"?

14 A. Yes.

15 Q. Do you know what document that refers to?

16 A. I would have to look in the binder. No, I
17 don't remember.

18 Q. Okay.

19 A. Can I?

20 Q. Well, not right now.

21 A. Okay.

22 Q. Let me ask, is it your understanding that
23 there's a document labeled in one of the binders called
24 FDA 24-Hour Summary?

25 A. That would be my understanding.

1 Q. Okay.

2 A. Uh-huh.

3 Q. But sitting here, you're not sure what
4 document this refers to?

5 A. No, I'm not.

6 Q. Okay. And, Doctor, a little further down it
7 says, "FDA Executive Summary." Do you know specifically
8 what document that refers to?

9 A. I do not.

10 Q. Okay. And, Doctor, the last item on the page
11 says "FDA Stress Urinary Incontinence." Do you know
12 what document that refers to?

13 A. I'm not certain, but I want to think that's
14 the document stating that the mid-urethral sling is an
15 acceptable treatment for stress urinary incontinence.

16 Q. So, Doctor, it's your testimony that FDA
17 stress urinary incontinence is an FDA document saying
18 that mid-urethral slings are safe and effective?

19 A. I had best look at it before I testify that's
20 definitely. May I take the time to find it?

21 Q. Why don't we do that on a break. Why don't we
22 see if we can locate that document.

23 A. All right.

24 Q. I'll admit from my side looking at a document
25 that just says FDA stress urinary incontinence, it's

1 very difficult to know what that document refers to; is
2 that fair?

3 A. That's fair.

4 Q. And, Doctor, the -- about half the documents
5 on this page start with the term "FDA"; is that correct?

6 A. That is correct.

7 Q. Okay. And how did you determine which FDA
8 documents to include in this reliance list?

9 A. Those were provided to me by counsel.

10 Q. Okay. And, Doctor, what significance, if any,
11 do these FDA documents have in your opinions in this
12 case?

13 MR. KOOPMANN: Object to the form.

14 THE WITNESS: Well, the specific document that
15 is most relevant, it was their press release stating
16 that mid-urethral slings are safe and effective.

17 BY MR. JACKSON:

18 Q. And why is that the most significant?

19 A. Because that's my understanding of my expert
20 opinion is that the TVT-O is safe and effective, and the
21 FDA agrees with me.

22 Q. Doctor, do you believe that -- sorry. Strike
23 that.

24 Doctor, do you believe that any statements the
25 FDA has made supporting the safety and efficacy of the

1 TVT obturator device, do you, in fact, support the
2 safety and efficacy of the TVT obturator device?

3 (Reporter clarification.)

4 Q. Doctor, do you believe that statements made by
5 the FDA supporting the safety and efficacy of the TVT
6 obturator device do, in fact, support the safety and
7 efficacy of the TVT obturator device?

8 MR. KOOPMANN: Object to the form.

9 THE WITNESS: They do support the safety. But
10 the actual safety and effectiveness is -- my opinion is
11 derived from review of the literature more so than an
12 FDA statement.

13 BY MR. JACKSON:

14 Q. Okay. Doctor, did you consider any statements
15 made by the FDA in forming your opinion in this case?

16 A. Well, yes, it's considered. It's on my
17 reliance list, and I believe it supports it, yes.

18 Q. Doctor, do you believe any statements made by
19 the FDA concerning the safety of the TVT obturator
20 device provide significant support for your opinions in
21 this case?

22 MR. KOOPMANN: I'll object to the form.

23 THE WITNESS: It was not my principal source
24 for forming my opinion, so it's hard for me to define
25 significant. I -- it was part of my opinion, but of

1 minimal significance.

2 BY MR. JACKSON:

3 Q. And, Doctor, just generally in regards to the
4 drafting of your report in this case, was it something
5 where you sat down and wrote all 19 pages at once or did
6 you sort of work as you went along?

7 A. I worked as I went along.

8 Q. Okay. And, Doctor, were you -- strike that.

9 Doctor, did you sort of go section by section
10 or just sort of -- how did you go about drafting your
11 report?

12 A. Yes. I started with the introduction and then
13 I worked section by section. But I might have done a
14 few sections on the same day.

15 Q. And, Doctor, are there any opinions you intend
16 to offer at trial about the TVT obturator device that
17 are not contained in this report?

18 A. No. My opinions are in this report.

19 Q. Doctor, do you intend to offer any opinions at
20 trial about the TVT retropubic device?

21 A. No.

22 Q. Okay. Doctor, would you agree with me that
23 you spend several pages in this report discussing the
24 TVT retropubic device?

25 A. I agree, yes.

1 Q. Doctor, why do you discuss the TVT retropubic
2 device in your TVT obturator report?

3 A. Because the TVT retropubic and the TVT
4 obturator, I generally feel, they're modifications of a
5 similar technique.

6 Q. Doctor, how are the TVT retropubic device and
7 the TVT obturator device different?

8 A. They employ a different mode of delivery, so
9 they -- the device is implanted in a different direction
10 in the body.

11 Q. Is it fair to say they have a different
12 surgical technique?

13 A. Yes, they do have a different surgical
14 technique, yes.

15 Q. Doctor, do you intend to opine at trial that
16 mid-urethral slings are the gold standard for SUI
17 surgical treatment?

18 A. I do, yes.

19 Q. Okay. And what is that based on?

20 A. The overwhelming body of evidence stating
21 their effectiveness, and their common use by urologists
22 and gynecologists for the treatment of stress urinary
23 incontinence. It is the principally performed
24 procedure.

25 Q. Okay. And, Doctor, do you intend to opine at

1 trial that the TVT obturator device is the gold standard
2 for SUI surgical treatment?

3 A. Only insofar as it is part of the class of
4 mid-urethral slings.

5 Q. Doctor, is it fair to say you can't point to
6 any specific documents that refer to the TVT obturator
7 as the gold standard for SUI treatment?

8 A. May I take one moment? I think most of my
9 articles point to mid-urethral slings in general as
10 being the gold standard, but there may be one that
11 states the TVT-O.

12 Q. If you don't mind, maybe you can look for that
13 over a break --

14 A. All right.

15 Q. -- and you can come back to that.

16 Doctor, why don't we say if you come across an
17 article that specifically refers to the TVT obturator as
18 the gold standard for SUI treatment, you'll make sure to
19 let me know while we're on the record today; is that
20 fair?

21 A. That's fair.

22 Q. Okay. Doctor, if I could ask you to turn to
23 page 6 of your report.

24 Doctor, I'm just looking at the last sentence
25 on this page that says, "The TVT was introduced in the

1 U.S. in 1998, and soon became the gold standard for SUI
2 surgical treatment."

3 Did I read that correctly?

4 A. Yes, you did.

5 Q. And in this sentence when you say "TVT," are
6 you just referring to the TVT retropubic non-Exact
7 product?

8 A. Yes.

9 Q. Doctor, when did the TVT retropubic device
10 become the gold standard for stress urinary
11 incontinence?

12 A. One cannot assign a specific date to that.

13 Q. Doctor you say here, "It soon became the gold
14 standard after it was introduced in 1998." Can you give
15 us an idea of what you mean by "soon" here?

16 A. Oh, 2004.

17 Q. So, Doctor, it's your testimony that in 2004
18 the TVT retropubic was the gold standard for SUI
19 treatment?

20 A. It's my testimony that the mid-urethral
21 polypropylene sling became the gold standard in
22 approximately 2004.

23 Q. Doctor, what is your definition of gold
24 standard?

25 A. The procedure to which all others should be

1 measured.

2 Q. And, Doctor, do you intend to opine at trial
3 that the design of the TVT obturator device makes it
4 safe and effective?

5 A. Yes.

6 Q. Okay. And, Doctor, do you have any experience
7 designing a medical device yourself?

8 A. Yes.

9 Q. And what experience is that?

10 A. Consulting with engineers on development of a
11 product for a postpartum hemorrhage, and offering my
12 opinions through surgeries, feedback to companies in the
13 use of their products in the human body.

14 Q. Okay. And, Doctor, do you have any experience
15 designing a medical device for SUI treatment?

16 A. Insofar that I offered feedback, yes. I have
17 not tried to design a device for commercial use. But in
18 my practice performing incontinence surgeries, there
19 have been times where I've had to modify present
20 instruments. So, yes, I've designed things to help me
21 in my surgeries.

22 Q. Doctor, just so I'm clear, when you say you've
23 designed things to help you in your surgeries, do you
24 just mean you've made modifications to devices for you
25 to use yourself?

1 A. Yes, uh-huh.

2 Q. Doctor, have you designed any medical devices
3 for SUI repair that have been commercialized for others
4 to use?

5 A. Not that I have brought to the commercial
6 production, no.

7 Q. And, Doctor, have you ever designed a
8 polypropylene mesh device of any kind?

9 A. Only insofar as I've provided feedback to the
10 reps that have introduced them to me, but, no, I have
11 not originally designed one, no.

12 Q. Okay. Doctor, the TVT obturator device is
13 inserted through something called the inside-out
14 approach; is that correct?

15 A. Correct.

16 Q. And do you intend to opine at trial that the
17 inside-out surgical technique is preferable to other
18 transobturator techniques?

19 A. I would intend to opine at trial it is
20 preferable in my hands to other techniques, but as a
21 general statement I would not opine that.

22 MR. JACKSON: Okay. We have been going for a
23 little over an hour. Why don't we take a break.

24 MR. KOOPMANN: Sure.

25 THE VIDEOGRAPHER: This marks the end of Disk

1 1, Volume I, videotaped deposition of Dr. Mareeni
2 Stanislaus. The time on the monitor the 2:23 p.m.

3 We are now off the record.

4 (Recess.)

5 (Exhibit 6-A was marked for
6 identification and attached hereto.)

7 (Exhibit 6-B was marked for
8 identification and attached hereto.)

9 (Exhibit 6-C was marked for
10 identification and attached hereto.)

11 (Exhibit 6-D was marked for
12 identification and attached hereto.)

13 (Exhibit 6-E was marked for
14 identification and attached hereto.)

15 (Exhibit 6-F was marked for
16 identification and attached hereto.)

17 (Exhibit 6-G was marked for
18 identification and attached hereto.)

19 THE VIDEOGRAPHER: We are back on the record.

20 This marks the beginning of Disk 2, Volume I, in the
21 videotaped deposition of Dr. Mareeni Stanislaus. The
22 time on the monitor is 2:36 p.m. We're back on the
23 record.

24 MR. JACKSON: While we were off the record we
25 marked as Exhibit 6-A through 6-G binders that

1 Dr. Stanislaus brought with her.

2 6-A is titled "SUI Mesh Documents, Binder 1."

3 6-B is titled "TVT Company Documents." 6-C is titled

4 "TVT-O Company Documents." 6-D is titled "TVT Medical

5 Literature." 6-E is titled "TVT Company/FDA Documents."

6 6-F is titled "SUI Mesh Documents, Binder 2." And 6-G

7 is titled "TVT literature and Position Statements."

8 Q. Dr. Stanislaus, have you been able to locate
9 anything indicating what the TVT stress urinary

10 incontinence document in the reliance list may be?

11 A. I'm sorry. Which one were you referring to?

12 Q. I'm on the tabbed page, the reliance list.

13 A. Yes.

14 Q. The last document is entitled "FDA Stress

15 Urinary Incontinence." Have you yet been able to

16 determine what that document refers to?

17 A. No.

18 Q. Okay. Thank you.

19 Doctor, would you agree with me that it's

20 appropriate for a physician who is going to implant the

21 TVT-O device to have read the instructions for use prior

22 to implanting the device?

23 A. At some point, yes, the instructions for use.

24 Q. It doesn't need to be right before they

25 implant it.

1 A. Yes.

2 Q. But would you agree they would need to have
3 read it prior to implanting the device?

4 A. Yes.

5 Q. And, Doctor, have you personally read the
6 TVT-O instructions for use prior to implanting the
7 device?

8 A. Yes.

9 Q. And, Doctor, is it appropriate for a physician
10 to rely on those TVT-O instructions for use to provide a
11 list of known risks associated with the TVT-O device?

12 A. No, it is not appropriate.

13 Q. And why not?

14 A. Because surgeons should rely on their training
15 to know how to perform a procedure, their training being
16 their training in medical school, residency, and in
17 practice. They should also rely on discussions with
18 their colleagues and on literature reports to really
19 determine the way to perform a procedure.

20 Q. Okay. Doctor, would you agree with me that
21 the TVT-O IFU is one of many pieces of information a
22 physician should consider to determine the risks of the
23 TVT-O device?

24 A. It is one of many, but it really should not be
25 the place you look for risks of a device.

1 Q. Okay. Doctor, do you believe the instructions
2 for use for the TVT obturator is an important document?

3 MR. KOOPMANN: Object to the form.

4 THE WITNESS: Important is a very subjective
5 thing, but yes. I mean, it's an important document,
6 sure.

7 BY MR. JACKSON:

8 Q. Doctor, in your practice as someone who
9 implants the TVT obturator device, do you consider the
10 TVT-O IFU an important tool in learning about risks?

11 A. No.

12 Q. Okay. So, Doctor, why did you discuss the
13 TVT-O IFU in your report?

14 MR. KOOPMANN: Object to the form.

15 THE WITNESS: Because it was my understanding
16 that Plaintiffs' experts may refer to the IFU. I
17 thought it would be an important thing to discuss.

18 BY MR. JACKSON:

19 Q. But, Doctor, you don't independently think
20 it's an important thing to discuss?

21 MR. KOOPMANN: Object to the form.

22 THE WITNESS: Sorry. To discuss in what
23 context?

24 BY MR. JACKSON:

25 Q. Doctor, do you believe the instructions for

1 use for the TVT obturator is relevant to assessing the
2 safety of the TVT obturator?

3 A. No, I don't actually believe that.

4 Q. Okay. And, Doctor, is it your testimony that
5 you only included a section on the TVT-O instructions
6 for use in your report because you said you think
7 Plaintiffs' experts think it's important?

8 A. Yes, that is why. And I -- yes, that is why.

9 Q. Okay.

10 A. Uh-huh.

11 Q. Doctor, what opinions do you intend to offer
12 at trial about the TVT-O instructions for use?

13 A. What I've outlined in my report.

14 Q. And, generally, what is your opinion with
15 regard to the TVT-O IFU in this case?

16 A. Well, that it's a document that's explains
17 what the device is and how it's to be used.

18 Q. Do you hold an opinion in this case that the
19 TVT-O IFU is sufficient with regard to the information
20 that it provides about the TVT-O device?

21 A. Yes. It's an instructions for use document,
22 and it provides sufficient information on how to use it.

23 Q. Doctor, do you believe it's a company's
24 response -- strike that.

25 Doctor, do you believe it's Ethicon's

1 responsibility to provide -- strike that.

2 Doctor, do you believe it's Ethicon's
3 responsibility to warn of the risks associated with the
4 TVT-O device?

5 A. It is -- well, anyone that knows of a risk of
6 a device has an ethical responsibility to report risks;
7 so, in that sense, yes. But I would suggest that they
8 would need to limit it to risks that are specific to the
9 device that they're making.

10 Q. Okay. Doctor, would you -- would you agree
11 with me that synthetic mesh carries additional risks
12 that are not present in other SUI treatments?

13 A. Yes, there are different risks.

14 Q. But the risks that come with polypropylene
15 mesh surgery that are not associated with autologous
16 fascial slings, for example.

17 A. Yes.

18 Q. What are some of those risks?

19 A. Exposure of the polypropylene material.
20 That's the principal one.

21 Q. Okay. And, Doctor, would you agree that
22 polypropylene mesh because it's a synthetic material can
23 cause a foreign body response?

24 A. Yes, any synthetic material will cause a
25 foreign body response as it is a foreign body.

1 Q. Doctor, just a minute ago you mentioned
2 polypropylene -- I'm sorry, Doctor, you mentioned just a
3 minute ago mesh exposure, correct?

4 A. Yes.

5 Q. And is your understanding that mesh exposure
6 and mesh erosion are two different concepts?

7 A. I do use them differently for the most part.

8 Q. Okay -- I'm sorry.

9 What's the difference in your understanding?

10 A. Exposure is visibility of the mesh externally.
11 So exposure through the vaginal mucosa. And erosion I
12 generally consider it to be eroding into an internal
13 organ, so -- such as the bladder or the urethra.

14 Q. Okay. Doctor, do you believe that the
15 implantation of the TVT device can cause chronic
16 inflammation?

17 A. It's a, generally, a very rare event but
18 chronic inflammation can occur, yes.

19 Q. Doctor, do you -- strike that.

20 Doctor, what's the difference between chronic
21 pain and transient pain following a surgery in your
22 practice?

23 A. Oh, in my practice? Chronic pain would be
24 pain that lasted beyond three months postoperatively.

25 Q. Okay. And is transient pain just normal

1 postoperative pain?

2 A. Transient pain is a pain of short duration
3 and, yes, that would typically be immediately related in
4 time to the surgery. So postoperatively, yes.

5 Q. Is it fair to say that transient pain resolves
6 and chronic pain continues for at least longer than
7 three months?

8 A. Correct. Yes, that would be fair to say.

9 Q. And, Doctor, would you -- would you agree with
10 me that other physicians in your field would have a very
11 similar definition of chronic versus transient pain?

12 A. I imagine so. I haven't discussed it
13 specifically, but I imagine so, yes.

14 Q. Okay. Doctor, is there a significant
15 difference between chronic postoperative pain that may
16 last longer than three months and transient postsurgical
17 pain?

18 A. Well, I mean by definition they're different
19 in length of time. So, yes, there's a difference and
20 it's significant, sure.

21 Q. Okay. Doctor, you cite a lot of literature in
22 your report, correct?

23 A. Yes, I do.

24 Q. And, just generally, in your report do you
25 cite any literature that tracks chronic long-term pain

1 following the TVT obturator?

2 A. I do believe the meta-analysis discuss pain
3 outside the postop period, yes, so I do, uh-huh.

4 Q. Can you name a study, for example, that you
5 believe tracks chronic long-term pain after the TVT-O
6 device?

7 A. The Ford study and the Cochrane review.

8 (Reporter clarification.)

9 A. The Ford study and the Cochrane review. The
10 Angioli study as well.

11 Q. Doctor, is there a randomized clinical trial
12 anywhere that has patient safety as a primary endpoint?

13 A. Yes.

14 Q. Can you give me an example of the study?

15 A. The Angioli study.

16 Q. And patient safety is a primary endpoint in
17 the Angioli study?

18 A. Yes, it was one of the primary endpoints,
19 uh-huh.

20 Q. Doctor, are there studies that track
21 dyspareunia, or painful sexual intercourse, as a primary
22 endpoint?

23 A. I really would have to review my reliance
24 list. I don't remember the specifics of the exact
25 primary endpoints of all these studies. I think

1 dyspareunia would be lumped into pain. So insofar as it
2 was lumped in, yes, there are studies.

3 Q. Are you aware of any studies that specifically
4 look at pain with intercourse or you think they'd just
5 all be lumped in with pain generally?

6 A. I -- let me rephrase it. I do think there is
7 a couple in here that specifically refer to dyspareunia,
8 yes.

9 Q. And can you name any of those studies here?

10 A. It would take me a moment to look through. So
11 no. If you give me a moment, I will look through and
12 show you.

13 Q. Sure.

14 (Pause while witness peruses documents.)

15 A. Specific to dyspareunia?

16 Q. Doctor, I tell you what, is that something we
17 can come back to and you can maybe check on a break?
18 Would that be okay?

19 A. Yes, that would be okay.

20 Q. Doctor, would you agree with me that one or
21 more revision surgeries may be necessary to treat
22 adverse reactions after a TVT-O implant?

23 A. Yes, revision surgery is sometimes necessary.

24 Q. And sometimes that can be more than one
25 revision surgery?

1 A. Incredibly rarely. I mean, TVT-O has the
2 lowest risk of requiring revision surgery of any
3 incontinence procedure. But, yes, it can --

4 Q. And what's --

5 A. -- be done more than once.

6 Q. I'm sorry.

7 And, Doctor, what's your basis for saying that
8 TVT-O has the lowest rate of complications?

9 A. The Cochrane review suggested a -- that a less
10 than 3 percent risk of exposure --

11 Q. Okay.

12 A. -- and a low rate of urinary retention. My
13 clinical experience between the retropubic and the
14 obturator is there's less retention with the obturator.
15 But, yes, there's literature showing that it's got a
16 very, very low complication rate and reoperation rate.

17 Q. Okay. And, Doctor, are you aware of any
18 literature showing that the TVT-O has higher rates of
19 complications than the 3 percent erosion rate you just
20 mentioned?

21 A. Oh, yes, there are studies. But, you know, I
22 tried to look at the high-quality studies.

23 Q. Okay. Doctor, is it your testimony that
24 studies that show a higher than 3 percent rate of
25 complications with the TVT-O are not high-quality

1 studies?

2 A. No, not -- no, that is not my testimony. I am
3 sure there are some studies that show a higher than
4 3 percent rate. But I believe the higher quality
5 studies show approximately 3 percent or less rate.

6 Q. Doctor, do you believe that the entire TVT
7 obturator can be removed after it's ingrown into a
8 woman's tissues?

9 A. I -- I believe that would be exceedingly
10 difficult. I suppose it's possible --

11 Q. Okay.

12 A. -- but not worth doing so.

13 Q. Is it fair to say it might require aggressive
14 dissection to get an entire TVT obturator out after its
15 been ingrown?

16 A. It would be fair to say that there is no
17 reason to ever aggressively dissect and remove an entire
18 TVT-O. But if that was one's desire, yes, it would
19 require extensive dissection.

20 Q. Doctor, have you personally performed surgery
21 to take TVT device -- I'm sorry. Strike that.

22 Doctor, have you personally performed revision
23 procedures on TVT obturator devices?

24 A. Yes, I have.

25 Q. And about how many revision procedures have

1 you performed on TVT obturator devices?

2 A. Specific to the TVT-O, I don't remember
3 exactly. Not very many. Perhaps two or three.

4 Q. And, Doctor, were those two or three instances
5 something where you were just trimming the mesh or were
6 they a more advanced removal procedure?

7 A. Again, one would have to define advanced
8 removal. One of them was trimming the mesh. One of
9 them involved some dissection to remove most of the
10 visible -- sorry -- most of the mesh up to a distance of
11 a couple of centimeters either way. So I suppose that's
12 extensive, uh-huh.

13 Q. And, Doctor, have you ever removed a TVT
14 obturator in its entirety?

15 A. No, I have not.

16 Q. Do you know anyone who ever has?

17 A. No, I do not.

18 Q. Doctor, the way to manage complications with a
19 TVT-O device is typically to remove a portion of the
20 mesh; is that correct?

21 MR. KOOPMANN: Object to form.

22 THE WITNESS: Not necessarily, no. It depends
23 on what the complication is.

24 BY MR. JACKSON:

25 Q. Okay. Doctor, if a patient has a mesh erosion

1 or an exposure of the TVT-O device, is a way to manage
2 that complication to typically remove part of the
3 device?

4 A. The first treatment you would use would be
5 estrogen cream to promote vaginal healing and
6 epithelialization. But if that is not effective,
7 certainly portions of the mesh can be removed.
8 Typically, though, that can just be done in the office.

9 Q. Okay. And if a physician is removing a
10 portion of a TVT-O device, the physician has to make a
11 judgment call about how much of the device to remove,
12 correct?

13 A. Every time a surgeon enters the operating room
14 we make multiple extensive judgment calls with every
15 step we make, with every cut we -- we perform. So, yes,
16 absolutely.

17 Q. Okay. So you'd certainly agree that the
18 amount of mesh that a surgeon was removing is a judgment
19 call?

20 A. Well, yes, as well as is the decision to
21 perform incontinence surgery in the first place, yeah,
22 sure.

23 Q. And if a doctor decides to only remove a small
24 portion of a mesh, you're certainly not here to fault a
25 doctor for choosing how much mesh to remove, correct?

1 MR. KOOPMANN: Object to form.

2 THE WITNESS: That's -- it seems a rather
3 hypothetical situation, but I don't think I was asked to
4 fault a physician for any of their specific decisions,
5 no.

6 BY MR. JACKSON:

7 Q. Okay. And, Doctor, do you specifically treat
8 patients for chronic pain following TVT obturator
9 surgery?

10 A. Well, I have not had any patients with chronic
11 pain in -- following TVT obturator surgery in my
12 practice. Would I be willing to treat them? Certainly.

13 Q. Okay. And, Doctor, you mentioned that on two
14 or three occasions you have performed revision
15 procedures of TVT obturators; is that correct?

16 A. Yes, that is correct.

17 Q. And are those revision procedures something
18 you report to the FDA as adverse events?

19 A. No, I did not report those.

20 Q. And, Doctor, on the two or three TVT-O
21 revision procedures you've performed, did you perform
22 any tests on the mesh that was removed?

23 A. I did not, no. Well, other than, you know,
24 looking at it visually. Certainly I had to look at
25 everything. It was -- I imagine that the specimen was

1 sent to pathology. I didn't send it away for any
2 specific testing, if that's what you mean.

3 Q. Okay. Are you aware of whether those
4 specimens were sent to pathology or are you just
5 guessing?

6 A. Specimens are always sent to pathology, so
7 they would have been, yeah, uh-huh.

8 Q. And would you have reviewed those pathology
9 reports?

10 A. Yes.

11 Q. Do you remember anything specific about those
12 pathology reports?

13 A. They were unremarkable, so, no, I do not.

14 Q. Doctor, are you aware of underreporting of
15 adverse events in your profession?

16 MR. KOOPMANN: Object to form.

17 THE WITNESS: Adverse events occur every day.
18 Not everything is reported.

19 BY MR. JACKSON:

20 Q. Doctor, have you ever tested a TVT obturator
21 mesh for degradation?

22 A. Yes, I've looked at it. I've seen it when
23 I've had to go in on repeat procedures, sure. It seems
24 to be very well intact when I've seen it in human
25 bodies, sure.

1 Q. And that's just based on your visual
2 inspection without any instruments; is that correct?

3 A. My visual inspection, my palpation, and, of
4 course, you know, its -- its effectiveness in the body
5 over long-term.

6 I mean, I have patients now that I have been
7 seeing since 2002, and their meshes are still in place.
8 So presume they are still there working without
9 degradation.

10 Q. And, Doctor, when you say you've tested a
11 TVT-O device for degradation, your concept for testing
12 there is you visually inspected it and not seen any
13 degradation, and the device is still working in the body
14 so there must not have been any degradation; is that
15 correct?

16 A. Yes, it would be -- my personal testing of it
17 would be a clinical evaluation of the product over time,
18 yes.

19 Q. Do you believe there's a clinical significance
20 to degradation?

21 A. I don't really believe that it's occurring.
22 But if it were occurring, the clinical significance
23 would be the procedure would no longer work.

24 Q. And so because the procedure's still working
25 there must not have been any degradation; is that

1 correct?

2 A. That's correct, yes.

3 Q. Okay. Doctor, are you familiar with the
4 chemical process of oxidative degradation, whether you
5 agree with it or not?

6 A. I'm sure, uh-huh, yes.

7 Q. And, Doctor, have you ever looked at
8 polypropylene mesh under a microscope?

9 A. No, I have not. I've seen pictures of it
10 described, but, no, I haven't personally.

11 Q. Doctor, have you ever asked a pathologist
12 about polypropylene degradation?

13 A. No. I speak with pathologists all the time,
14 but that hasn't really been a question that I would
15 think to ask. Because the times I've removed
16 polypropylene, it looks perfectly intact and undegraded.
17 So, no, I have not specifically asked that question, no.

18 Q. Doctor, are you aware of published
19 peer-reviewed scientific literature that suggests that
20 polypropylene mesh degrades in the body by oxidative
21 degradation?

22 A. Yes, I am aware of literature that states that
23 polypropylene degrades.

24 Q. And you've never -- is it fair to say you've
25 never asked a pathologist whether the polypropylene mesh

1 does, in fact, degrade inside the body?

2 A. As I said, I had no reason to ask a
3 pathologist that question. I'm aware of literature that
4 states that it degrades, but I'm also aware of
5 literature that states that it does not degrade. It
6 wasn't really clinically relevant to me to ask a
7 pathologist whether it's degrading.

8 Q. Okay. Doctor, do you know what type of
9 polypropylene is in the Ethicon SUI products?

10 A. Polypropylene. I think there's only one type.

11 Q. Okay. It's the same?

12 A. Right.

13 Q. And do you know who manufactures the actual
14 polypropylene? Not the mesh, the actual polypropylene.

15 A. And, once again, that wasn't particularly
16 clinical relevant to me. I did see somewhere in these
17 documents that it may have been manufactured by Sinoco.
18 But, again, I couldn't tell you with 100 percent
19 certainty that that's where it came from.

20 Q. And, Doctor, do you know whether there are
21 antioxidants added to Ethicon's propylene?

22 A. Oh, yes, there are, uh-huh.

23 Q. And do you know whether pure polypropylene
24 without antioxidants can degrade?

25 A. Gosh, I haven't ever used pure polypropylene

1 without the antioxidants so I don't know.

2 Q. Okay. Doctor, have you ever performed any
3 independent studies to determine whether polypropylene
4 degrades?

5 A. As I said, I've, you know, looked at the
6 material as I've used it, seen it in the body over time,
7 but I haven't published any papers, no.

8 MR. JACKSON: If we could mark this Exhibit 8,
9 please.

10 (Exhibit 8 was marked for
11 identification and attached hereto.)

12 BY MR. JACKSON:

13 Q. Doctor, I'm going to represent to you that
14 this is a version of the instructions for use for the
15 TVT obturator. It says "2003" on the bottom of the
16 first page.

17 A. Yes, it does.

18 Q. I believe this version was in effect from 2003
19 to 2004. This one is on your reliance list, I'll tell
20 you that.

21 Doctor, if I could ask you to turn to the page
22 of this document that says 5 in the middle of the
23 bottom.

24 A. Okay.

25 Q. And the number stamped at the bottom

1 right-hand corner ends in 0834. Are you on that page?

2 A. Yes, I am.

3 Q. Okay. Doctor, do you see the section in the
4 middle that says "Contraindications"?

5 A. Yes, I do.

6 Q. And it says, "As with any suspension surgery,
7 this procedure should not be performed on pregnant
8 patients. Additionally, because polypropylene mesh will
9 not stretch significantly, it should not be performed in
10 patients with future growth potential, including women
11 with plans for future pregnancy."

12 Did I read that correctly?

13 A. Yes, you did.

14 Q. Doctor, would you agree with me that this
15 version of the instructions for use doesn't say, for
16 example, that the TVT-O should not be used in obese
17 women?

18 A. No, it does not say it should not be used.

19 Q. It doesn't say it should not be used in women
20 who smoke?

21 A. Why would it say that? But, yes, no, it
22 doesn't say that.

23 Q. And it doesn't say it should not be used in
24 women with weak connective tissue?

25 A. Wouldn't that be terrible if we couldn't use

1 it in any of those women. They'd walk around leaking
2 urine all over the place. But, no, it does not say
3 that.

4 Q. Doctor, is it fair to assume that Ethicon
5 would have known that a certain -- a certain proportion
6 of the women implanted with the device would be obese?

7 MR. KOOPMANN: Object to form.

8 THE WITNESS: Well, insofar as the majority of
9 the U.S. population is trending towards obesity, and
10 that obesity is a risk factor for incontinence,
11 certainly this device should be expected to be used in
12 obese patients.

13 BY MR. JACKSON:

14 Q. Fair enough. And Ethicon did not say that
15 those women couldn't get this device, did they?

16 A. No. No, they didn't.

17 Q. Okay. And if Ethicon thought that those obese
18 women should not get the device, is that something they
19 would have put in their warning information?

20 MR. KOOPMANN: Object to form. Foundation.

21 THE WITNESS: I don't really feel that Ethicon
22 should put such a statement in their IFU. Whether they
23 would have, I -- I really don't know. Well, they
24 didn't, so they -- they didn't.

25 BY MR. JACKSON:

1 Q. Sure. And, Doctor, why don't you think such a
2 statement should have been put in the IFU?

3 A. Well, because for the reasons I stated
4 earlier, that obesity is a huge risk factor for
5 incontinence because incontinence is an incredible
6 public health problem for women.

7 Surgical procedures need to be developed and
8 exist for these women. The TVT-O device, in particular,
9 happens to be a much safer procedure for an obese woman
10 than other procedures. So I think it might be
11 misleading to put in an IFU that it shouldn't be used in
12 an obese woman.

13 Q. Doctor, the TVT obturator device is obviously
14 intended for women with stress urinary incontinence,
15 correct?

16 A. That is correct.

17 Q. As you said, many women with stress urinary
18 incontinence also have other comorbidities, correct?

19 A. That is absolutely correct, yes.

20 Q. And, Doctor, in your opinion, the TVT-O device
21 is a perfectly acceptable device for these women despite
22 their comorbidities, correct?

23 MR. KOOPMANN: Object to form.

24 THE WITNESS: In every situation a surgeon has
25 to consider the risks and benefits as they pertain to a

1 particular patient. So in the correct patient, a TVT-O
2 device is an acceptable device to use, yes.

3 BY MR. JACKSON:

4 Q. Doctor, can you give me an example of
5 comorbidity that you may see in a patient where you
6 would choose not to implant the TVT-O device?

7 A. Prior radiation to the pelvis.

8 Q. Okay. And why would prior radiation to the
9 pelvis indicate you to not implant the TVT-O device?

10 A. Because of poor tissue healing.

11 Q. Okay. And is that kind of common knowledge
12 that any surgeon would know?

13 A. Yes.

14 Q. Okay. Doctor, do you see the first bullet
15 point on this same page 5 under Warnings and Precautions
16 where it says, "Do not use Gynecare TVT obturator
17 procedure for patients who are on anticoagulation
18 therapy"?

19 A. I do.

20 Q. And is it fair to say a surgeon would not want
21 to implant the TVT-O device on a patient who's on
22 Xarelto, for example?

23 A. So a surgeon would not want to perform any
24 surgery on a patient that was on anti-coagulation,
25 including Xarelto. So, yes, that's not just limited to

1 the TVT-O.

2 Q. But certainly including the TVT-O?

3 A. Yes.

4 Q. And that's because the patient could start
5 bleeding during the procedure, right?

6 A. Absolutely, yes, uh-huh.

7 Q. Okay. And that is certainly common knowledge
8 among surgeons, correct?

9 A. Yes, it is.

10 Q. Okay. Doctor, are you offering yourself as an
11 expert in what should and what should not be included in
12 the TVT obturator devices warnings?

13 A. I am offering myself as an expert in -- in
14 that, yes.

15 Q. So you feel like you're an expert in what
16 should and should not be in TVT-O warnings?

17 A. Insofar as the warnings are directly related
18 to me as a surgeon, yes, I am an expert.

19 Q. Doctor, if I can ask you to turn to the next
20 page of this document, which says page 6, in the middle.
21 The last four in the bottom right-hand corner are 0835.
22 Do you see the adverse reaction section?

23 A. Yes.

24 Q. Okay. The second bullet point says,
25 "Transitory local irritation at the wound site and a

1 transitory foreign body response may occur. These
2 responses could result in extrusion, erosion, fistula
3 formation and inflammation."

4 Did I read that correctly?

5 A. Yes, you did.

6 MR. KOOPMANN: Object to the form.

7 BY MR. JACKSON:

8 Q. And, Doctor, we discussed the definition of
9 transitory to mean what would be typical postoperative
10 pain, correct?

11 A. Correct.

12 Q. And transitory pain is certainly different
13 from long-term chronic pain, correct?

14 A. Yes.

15 Q. And, Doctor, is there anywhere in this
16 warnings and precautions section or adverse reaction
17 section where it mentions long-term pain?

18 A. So it does not specifically state long-term
19 pain, but they do mention puncture of nerves. And it
20 also is common knowledge to any surgeon that any surgery
21 can result in a chronic long-term pain. So perhaps not
22 necessary to state that.

23 Q. Okay. Whether you believe it's necessary or
24 not, would you agree there's no specific mention of
25 long-term or chronic pain?

1 MR. KOOPMANN: Object to form.

2 THE WITNESS: Puncture of a nerve by inference
3 suggests long-term chronic pain. But, no, it does not
4 specifically state chronic pain here.

5 BY MR. JACKSON:

6 Q. Okay. And, Doctor, is there any mention of
7 acute pain?

8 A. Well, again, that -- it's common knowledge
9 that all surgeries cause acute pain. As I'm reading
10 this again now, transitory, local irritation equates to
11 pain in my definition. So it does refer to transient
12 pain, yes.

13 Q. Okay. And is transient pain the same as acute
14 pain in your practice?

15 A. Oh, yes, certainly.

16 Q. Okay. Doctor, would you agree with me that
17 there's no mention specifically of pain with intercourse
18 in the adverse reactions or the warnings and precautions
19 section of this document?

20 A. And, once again, that's just simply a known
21 factor when you're performing surgery in the pelvis that
22 dyspareunia is a potential event. So I don't know why
23 they would specifically put that in there, but I do not
24 see the specific word dyspareunia, no.

25 Q. Doctor, your testimony is that pain with

1 intercourse is known to pelvic surgeons who are going to
2 be implanting a mesh device?

3 A. Yes, that is my testimony.

4 Q. And so that it doesn't need to be included in
5 here because it's a known risk?

6 A. Of pelvic surgery, yes.

7 Q. Okay. Doctor, do you know whether there was
8 ever any language in the TVT IFU prior to 2015 to the
9 effect that there may be more than one revision surgery
10 required after implantation?

11 A. To my knowledge, prior to 2015, no. But,
12 again, that is, you know, sort of common knowledge that
13 if one has an adverse event from a procedure, that
14 revision surgeries need to be done. I mean, even
15 without using a tape I sometimes have to revise pelvic
16 surgery multiple times.

17 Q. Doctor, this document mentions that the TVT-O
18 should not be implanted in patients who are on
19 anticoagulation therapy, correct?

20 A. Correct.

21 Q. We said that's common knowledge.

22 A. Yes, that is correct.

23 Q. It's fair to say there's some common knowledge
24 that was included by Ethicon in this document, correct?

25 A. Yes, that is correct. But, again, if they

1 were to put in everything that's common knowledge, this
2 document would have to span years of training. It would
3 probably be 25,000 pages long. I don't think everything
4 I learned about common knowledge happened from a
5 one-page document.

6 Q. Doctor, the TVT-O device is designed to be
7 implanted without tension, correct?

8 A. Yes, that is correct.

9 Q. Okay. And, Doctor, when you're implanting a
10 TVT-O device, how do you determine whether there's any
11 tension on the device?

12 A. I place a dilator between the urethra and the
13 tape. And then as I'm removing the sheath, I make sure
14 that it doesn't move so that there's a little space
15 beneath the urethra.

16 Q. Doctor, is it your understanding that Ethicon
17 teaches surgeons how to properly tension the TVT
18 obturator device?

19 A. Well, yes, they did teach me in the lab, yes.

20 Q. Doctor, when Ethicon taught you in your TVT
21 obturator training how to tension or test for tension in
22 the TVT obturator device, did they teach you how to
23 account for women who are built differently?

24 A. I don't recall specifics regarding that. So
25 when I say Ethicon, I mean these are surgeons hired by

1 Ethicon to teach the procedure. And over time, you
2 know, you consult with surgeons about tensioning. And
3 in terms of implanting it in a specific anatomical type,
4 that is such an individual situation and decision, it
5 would really be not -- I don't really believe it would
6 be Ethicon's place to specifically teach that. It would
7 depend on my own knowledge of anatomy.

8 Q. Okay. Doctor, do you see the section on this
9 page, page 6, that says "Actions"?

10 A. Yes.

11 Q. The last sentence of that paragraph says, "The
12 material is not absorbed nor is it subject to
13 degradation or weakening by the action of tissue
14 enzymes."

15 Do you see that?

16 A. I do.

17 Q. Okay. And do you believe that's a true
18 statement?

19 A. I do believe that's a true statement, yes.

20 Q. Doctor, did you read any Ethicon documents
21 specifically dealing with dog studies and Prolene
22 sutures and degradation?

23 A. Yes, I did.

24 Q. And if Ethicon had documents that showed that
25 Prolene did, in fact, degrade, would this statement be

1 untrue?

2 A. Not necessary -- I mean, no, it depends on
3 what the clinical quality of the study was and how
4 relevant it is to use in this form.

5 Q. Doctor, did you read any testimony of a
6 Dr. Barbolt, who's an Ethicon employee, in connection
7 with your work in this case?

8 A. I'm not certain that -- that name is familiar,
9 but I'm not certain.

10 Q. Do you recall reading anything an Ethicon
11 employee named Dr. Barbolt may have said about
12 degradation?

13 A. Sorry, I don't recall.

14 Q. Doctor, to your knowledge have any Ethicon
15 employees testified under oath that the polypropylene
16 mesh in the TVT obturator device does, in fact, degrade?

17 A. That it does in fact degrade?

18 Q. Yes.

19 A. I -- so I, to my knowledge, I don't actually
20 know that. But I'm not quite sure why that would be
21 relevant to my opinion.

22 Q. Doctor, one of the opinions you hold in this
23 case is that the mesh in the TVT obturator device does
24 not degrade, correct?

25 A. Correct.

1 Q. And you just said that you don't believe that
2 it's relevant whether an Ethicon employee stated that it
3 does degrade?

4 A. Correct. Well, I don't know who that employee
5 is. I don't know what studies he reviewed or what was
6 the basis of his opinion. I mean, I've worked with the
7 material. I've seen it in the patient. I've been
8 practicing 25 -- 24 years as a physician. I've seen
9 Prolene. That's been around that long.

10 My experience would dictate that it doesn't
11 degrade. So, you know, yes, if that employee
12 specifically worked in that field and had done studies
13 and could show that to me, of course, that would be
14 relevant. But I don't know who this employee is.

15 Q. Doctor, if I could ask you to take out just
16 your report, which is Exhibit 1. And if I could ask you
17 to turn to Page 15, please.

18 Doctor, I'm looking at a section entitled,
19 "Plaintiffs' Theories are not Supported by the Published
20 Medical Literature or My Experience."

21 A. Yes.

22 Q. Doctor, the second sentence says, "Nor have I
23 seen any evidence of Prolene mesh degradation in my
24 clinical practice. I have not observed degradation of
25 the mesh in the instances in which I have implanted it."

1 Did I read that correctly?

2 MR. KOOPMANN: Object to form.

3 THE WITNESS: Yes.

4 BY MR. JACKSON:

5 Q. So, Doctor, is it your testimony that because
6 you have not seen mesh degradation when you're
7 implanting mesh that there must not be degradation?

8 MR. KOOPMANN: Objection, Counsel. You said
9 implanted," and it says "explanted." And then your
10 follow-up question was based on your misreading of that
11 sentence.

12 MR. JACKSON: That's my mistake. I apologize.
13 Let me strike that.

14 Q. Doctor, the second sentence of this paragraph
15 says, "Nor have I seen any evidence of Prolene mesh
16 degradation in my clinical practice. I have not
17 observed degradation of the mesh in the instances in
18 which I have explanted it."

19 Did I read that correctly?

20 A. Yes, you did.

21 Q. Okay. And is it your testimony that because
22 you have not observed degradation of explanted mesh in
23 the two to three instances you've explanted it, that it
24 must not be occurring?

25 MR. KOOPMANN: Object to form.

1 THE WITNESS: I have explanted different types
2 of polypropylene mesh on more than two to three
3 occasions. I was referring specifically to two to three
4 occasions of the TVT-O device. I do believe my greater
5 experience is relevant since the material is the same.
6 And, yes, I am testifying that my -- that the fact that
7 I have not observed degradation is the basis of my
8 statement.

9 There is also, however, data showing that
10 polypropylene does not degrade. And there are published
11 articles that also support my clinical impression.

12 BY MR. JACKSON:

13 Q. Doctor, you cite to a number of published
14 studies in your report, correct?

15 A. I do, yes.

16 Q. Are any of those studies specifically to laser
17 cut mesh?

18 A. To be honest, I'm not certain that they're
19 specific to -- oh, yes, yes, there are. There were some
20 studies with devices that were only made with the laser.
21 So I do think there are some in there specific to laser,
22 uh-huh.

23 Q. Okay. Doctor, would you agree with me that
24 there are -- well, strike that.

25 Doctor, are there any TVT-O specific studies

1 that you cite in your report that deal specifically with
2 laser cut mesh?

3 A. I don't think so.

4 Q. Doctor, are you offering any opinions that
5 there is a clinical significance -- clinically -- strike
6 that.

7 Doctor, are you offering an opinion that there
8 is a clinical significance between mechanically cut mesh
9 and laser cut mesh?

10 A. No, I am not offering opinion that there is a
11 difference clinically.

12 Q. Doctor, have you seen any Ethicon documents in
13 connection with your work in this case showing that the
14 mechanically cut mesh has a tendency to fray?

15 A. I think there were some documents with reports
16 from other surgeons suggesting fraying, but I don't have
17 any papers specifically suggesting that it does fray or
18 confirmation that it does fray.

19 Q. Have you seen documents showing that there is
20 particle loss where doctors are saying they believe this
21 is causing pain?

22 A. Gosh, I did see documents suggesting particle
23 loss, but, no, not that it was causing pain. Why would
24 it cause pain? But I have not reviewed every document
25 given to Ethicon.

1 We leave particles of Prolene in patients all
2 the time with Prolene suture and -- I mean, it's just a
3 commonly used material.

4 Q. Okay. And, Doctor, are you aware that
5 particle loss associated with the mechanical cut mesh
6 was a reason that Ethicon developed the laser cut mesh?

7 A. My understanding was that they developed a
8 laser cut mesh for ease of production. But I'm sure
9 that they were aware of particle loss. I mean because
10 physicians wrote in about it. But I don't see why they
11 would have used that as a reason. So, no, I was not
12 aware. Sorry.

13 Q. Okay. And, Doctor, do you know whether
14 Ethicon performed any studies to determine whether there
15 was or was not clinical significance to any particle
16 loss?

17 A. I would imagine that study would be very
18 difficult to design. But, no, I'm not aware of a
19 specific study.

20 Q. And, Doctor, you mentioned that you have
21 implanted approximately 150 TVT obturator devices in
22 your career, correct?

23 A. That is correct.

24 Q. And do you have a sense of how that breaks
25 down between mechanically cut and laser cut mesh?

1 A. Forgive me. I do not. They were fairly
2 interchangeable to me. I just used which device was
3 presented to me.

4 Q. And, Doctor, to your knowledge, does Ethicon
5 still sell both the laser cut and mechanically cut TVT
6 obturator devices?

7 A. Yes, they do.

8 Q. Doctor, if I could ask you to turn to page 7
9 of your report. And at the top of this page it says,
10 "The TVT is a monofilament, large pore, (Type 1),
11 lightweight, Prolene polypropylene mesh sling that is
12 placed without tension under the mid-urethra."

13 Did I read that correctly?

14 A. Yes, you did.

15 Q. And is it fair to say you'd characterize the
16 TVT obturator mesh as macroporous?

17 A. Yes.

18 Q. Is macroporous safer than microporous mesh for
19 the T -- for the SUI indication?

20 A. Yes.

21 Q. And would you agree with me that smaller pore
22 microporous mesh is less desirable than macroporous mesh
23 for the SUI indication?

24 MR. KOOPMANN: Object to form.

25 THE WITNESS: I'm not aware of any currently

1 available meshes for SUI that are microporous, but they
2 would be less desirable than a macroporous mesh.

3 BY MR. JACKSON:

4 Q. Doctor, what support do you have for the
5 statement that the mesh in the TVT obturator is a large
6 pore mesh?

7 A. There is a Amid classification that states
8 that any mesh, any pore size, greater than 75 microns is
9 macroporous.

10 Q. And, Doctor, the Amid classification was
11 developed in the hernia application, correct?

12 A. Yes, it was.

13 Q. Doctor are you aware of any Ethicon documents
14 where Ethicon employees state that the Amid
15 classification is no longer valid?

16 A. No, I was not aware of such a document.

17 Q. Doctor, do you believe you've done enough due
18 diligence to offer the opinion that the TVT-O mesh is
19 macroporous?

20 A. Yes.

21 Q. And, Doctor, what have you done to determine
22 that the TVT-O mesh is macroporous?

23 A. I've looked at it. And at some point I've
24 measured it with a ruler. That's what I would say.

25 Q. And did you look at the mesh and measure it

1 with a ruler as part of your work in this case or is
2 that something you would have done prior to becoming
3 involved in this case?

4 A. It's something I would have done prior to
5 becoming involved in this case.

6 Q. Okay. And do you remember when you measured
7 the TVT mesh with a ruler how big the pore sizes were?

8 A. I -- I probably do not remember what it was
9 from that date, but the pore size is 1300 -- 1379
10 microns.

11 Q. And that's based on your measurements with a
12 ruler prior to becoming involved in this case?

13 MR. KOOPMANN: Object to form.

14 THE WITNESS: That statement is based on the
15 published pore size. My recollection of measuring it
16 with a ruler is it was more than a thousand microns
17 because I was comparing different meshes at the time.

18 MR. JACKSON: Why don't we take another break.

19 MR. KOOPMANN: Sure.

20 THE VIDEOGRAPHER: The time on the monitor is
21 3:36 p.m. We are now off the record.

22 (Recess.)

23 THE VIDEOGRAPHER: We are back on the record.
24 The time on the monitor is 3:47 p.m.

25 BY MR. JACKSON:

1 Q. Doctor, what percentage of your current
2 practice involves pelvic floor surgery?

3 A. Approximately 40 percent.

4 Q. And what comprises the remaining 60 percent of
5 your practice?

6 A. Obstetrics and -- well, routine gynecology.

7 Q. Doctor, on page 1 of your report, Exhibit 1,
8 you note in the education and training section that you
9 have a special interest in pelvic floor surgery; is that
10 correct?

11 A. That is correct.

12 Q. What does it mean you have a special interest
13 in pelvic floor surgery?

14 A. Well, I enjoy taking care of these patients.
15 Women in this community seek me out for pelvic floor
16 procedures. And I keep up on the literature and the
17 data in my field --

18 Q. Okay.

19 A. -- so...

20 Q. And, Doctor, if one of your patients is going
21 to undergo sling surgery for stress urinary
22 incontinence, how do you choose between a retropubic
23 procedure and a transobturator procedure?

24 A. I choose based on their prior surgical
25 history, their age and activity level, and sometimes

1 factor into their urodynamic studies.

2 I counsel patients generally on both
3 techniques, though. And I do allow their assessment of
4 what the potential adverse events are to help me guide
5 which approach I use.

6 Q. Okay. And how do the patients get information
7 on the relative adverse events of the retropubic versus
8 the transobturator approach?

9 A. I discuss it with them verbally at one of
10 several consultations. And I encourage them to look at
11 the different patient brochures, and to talk to other
12 women who have had incontinent surgery.

13 Q. You certainly don't expect patients to keep
14 abreast of the most recent medical literature, do you?

15 A. No, I do not.

16 Q. Okay. Does the TVT-O have adverse events
17 associated with it that are not associated with the
18 retropubic TVT device?

19 A. Yes.

20 Q. Such as?

21 A. Such as groin pain.

22 Q. And does the retropubic TVT have adverse
23 events associated with it that are not typically
24 associated with the obturator device?

25 A. Yes. Although, with that, it's more that the

1 retropubic approach has a greater incidence of adverse
2 events than the obturator approach.

3 Q. Okay. Is it your understanding that the
4 retropubic approach has a higher percentage of bladder
5 perforations associated with it than the transobturator
6 approach?

7 A. That is correct.

8 Q. And is it your understanding that the TVT
9 obturator approach has a higher percentage of groin pain
10 associated with it than the retropubic TVT approach?

11 A. That is my understanding, yes.

12 Q. And, Doctor, are those examples of different
13 morbidity associated with the TVT obturator and the
14 TVT retropubic?

15 A. Yes, they are examples, uh-huh.

16 Q. Okay. So is it fair to say that a higher
17 incidence of groin pain associated with the TVT
18 obturator device is a morbidity that the obturator
19 device has and the retropubic device does not have?

20 A. Well, that is a true statement. You know,
21 when counseling a patient you have to sort of weigh the
22 relative importance of different morbidities. For
23 example, puncturing a bladder, or a bowel, or a major
24 blood vessel could be a more significant morbidity than,
25 say, a groin pain.

1 Q. Well, Doctor, for a patient that comes into
2 your office for a prospective SUI repair surgery, how do
3 they know whether groin pain or bladder perforation is a
4 greater concern?

5 A. Principally from my counseling to them. But
6 any reasonable person with a reasonable level of
7 education would understand that puncturing a -- another
8 organ is probably a more significant complication than
9 groin pain. But, yeah, it would be from my discussion
10 with them.

11 Q. Okay.

12 A. Lead them in that direction, uh-huh.

13 Q. Doctor, when you say that a bladder
14 perforation is a more significant complication than
15 groin pain -- is that what you said; is that correct?

16 A. I did say that, yes.

17 Q. Okay. And do you believe that -- let me back
18 up.

19 Doctor, do you believe in that respect that
20 the TVT obturator is an improvement on the retropubic
21 TVT device?

22 A. In that respect, yes, it is an improvement,
23 absolutely.

24 Q. Doctor, how do you stay informed on the
25 relative advantages of the TVT retropubic and TVT

1 obturator products?

2 A. So there has been so much published data on
3 both of them that I do feel both of them are safe. But
4 in terms of keeping up to date on what's coming out
5 newly, I read The Green Journal, The Gray Journal, and I
6 do watch for pronouncements by AUGS.

7 Q. And, Doctor, just briefly, when you say The
8 Green Journal and The Gray Journal, what do those refer
9 to?

10 A. That's the Journal of the American College of
11 OB-GYN. That's The Green Journal. The Gray Journal is
12 AJOG, which is the American Journal of OB-GYN.

13 Q. Thank you.

14 Can we mark this as an exhibit, please. I
15 believe we are on 9.

16 (Exhibit 9 was marked for
17 identification and attached hereto.)

18 BY MR. JACKSON:

19 Q. Doctor, did you discuss an article by Teo,
20 et al., in your report?

21 A. I don't believe that I did.

22 Q. Doctor, have you read the article that's been
23 marked as Exhibit 9?

24 A. When was this from? 2011.

25 Q. Doctor, are you familiar with this study?

1 A. I'm trying to remember if I would have read it
2 at the time. I'm not familiar with it at the moment,
3 no.

4 Q. Okay. And, Doctor, this is from the Journal
5 of Urology. Is that a peer-reviewed article -- I'm
6 sorry -- strike that.

7 Doctor, is the Journal of Urology a
8 peer-reviewed journal?

9 A. Yes, it is, uh-huh.

10 Q. Doctor, do you see on the first page under the
11 Results section where 127 women were randomized to
12 either the TVT retropubic or the TVT obturator device?

13 A. Yes.

14 Q. And, Doctor, do you see the second sentence
15 under the Results section that says, "The study was
16 stopped early due to excess leg pain in the tension-free
17 vaginal tape obturator group"?

18 Do you see that sentence?

19 A. Sorry. Where was that?

20 Q. Under "Results" on the first page --

21 A. Yes.

22 Q. -- the second sentence. It says the --

23 A. Oh, yes, I do.

24 Q. -- "study was" --

25 A. Yes.

1 Q. Doctor, the second sentence under Results on
2 the first page says, "The study was stopped early due to
3 excess leg pain in the tension-free vaginal tape
4 obturator group."

5 Do you see that sentence?

6 A. I do.

7 Q. Okay. And, Doctor, further down in that same
8 Results paragraph there's a sentence that says, "More
9 women complained of leg pain after receiving a
10 tension-free vaginal tape-operator (26.4% versus 1.7%,
11 $p=0.0001$.)"

12 Did I read that correctly?

13 A. Yes, you did.

14 Q. Okay. So, Doctor, is it your understanding
15 that there was a statistically significant difference
16 between leg pain in the obturator group versus the
17 retropubic group in this study?

18 A. Yes, there is a statistically significant
19 difference. But as a clinician, it's very important to
20 differentiate between statistically significant and
21 clinically relevant, so...

22 Q. Doctor, is it your understanding that this
23 study was stopped early because of the leg pain in the
24 TVT obturator group?

25 A. That is what they state, yes.

1 Q. Okay. Could that be an indication of clinical
2 significance in the TVT obturator group?

3 MR. KOOPMANN: Object to the form.

4 THE WITNESS: The authors decided to stop the
5 study because of leg pain. But I would need to read
6 this more carefully to find out why they chose to study
7 it -- to stop it because of leg pain.

8 Having performed multiple TVT-O procedures,
9 the leg pain I've seen has been transitory and not
10 particularly troubling to the patients. So it would
11 seem unusual that they would need to stop the study
12 based on that.

13 And it also would appear, you know, just by
14 the technique that you would expect greater leg pain
15 with a procedure that involves an exit point in the leg.

16 BY MR. JACKSON:

17 Q. Okay. Thank you.

18 A. So...

19 Q. And, Doctor, is it fair to say you were not
20 familiar with this study at the time of -- the time you
21 wrote your report in this case?

22 MR. KOOPMANN: Object to form.

23 THE WITNESS: Yes, that would be fair to say.

24 MR. JACKSON: If we could mark this as
25 Exhibit 10.

1 (Exhibit 10 was marked for
2 identification and attached hereto.)

3 BY MR. JACKSON:

4 Q. Doctor, do you recall seeing this document
5 which we marked as Exhibit 10 before?

6 A. I do think I've seen it before.

7 Q. I'll represent to you it is on your reliance
8 list in this case.

9 A. Uh-huh.

10 Q. Do you see at the bottom of this case it says
11 Meng Chen is the associate medical director at Ethicon?

12 A. Yes, I do see that.

13 Q. Have you ever met her?

14 A. No, I have not.

15 Q. Have you reviewed any documents authored by
16 Meng Chen in addition to this one?

17 A. I do believe there are other documents, yes.

18 Q. Okay. And do you see that on January 29th,
19 2009 where Meng Chen is questioning whether or not the
20 general statement about transitory local irritation is
21 still sufficient?

22 A. Yes.

23 Q. And do you see what she says above that?

24 About an hour later, she tells Bryan, Lisa, "Pardon me,
25 from what I see each day, these patient experiences are

1 not 'transitory' at all"?

2 MR. KOOPMANN: Object to form.

3 THE WITNESS: Yes, I see that written here.

4 BY MR. JACKSON:

5 Q. Okay. And do you see she's talking about the
6 TVT IFU on tape extrusion, exposure and erosion?

7 MR. KOOPMANN: Object to form.

8 THE WITNESS: Uh-huh.

9 BY MR. JACKSON:

10 Q. Doctor, was that a "yes"?

11 A. Yes.

12 Q. Doctor, are you aware that Meng Chen
13 recommended that the IFUs be updated to reflect the kind
14 of calls she was getting about permanent pain, and
15 chronic pain, and inability to have intercourse?

16 A. Well, aware insofar as it's stated here, yes.

17 Q. Doctor, do you disagree with the worldwide
18 medical director of Ethicon if she said that these
19 things needed to be changed to update what was
20 happening?

21 MR. KOOPMANN: Object to form.

22 THE WITNESS: I'm a surgeon that is not in her
23 position as the associate medical director. She can
24 choose to put whatever information she feels necessary
25 in the IFU. So I -- it really isn't my position to

1 agree or disagree with her decisions there.

2 BY MR. JACKSON:

3 Q. But, Doctor, aren't you holding yourself out
4 as an expert in this case as to what should and should
5 not be included in the TVT warning information?

6 A. As the person to whom this IFU is directed,
7 yes, I am holding myself up as an expert. So in that
8 situation, yes, I am disagreeing that it would be
9 necessary to put that information in an IFU.

10 Now, her situation is different. She does not
11 have the experience with the product that I do and use
12 in clinical patients. So she might have come to it from
13 a different standpoint.

14 Q. Okay. Doctor, do you know that Meng Chen does
15 not have the clinical experience implanting the TVT-O
16 that you do?

17 A. Well, I have not reviewed her CV. But as the
18 associate medical director for a large company, I can't
19 imagine she's seeing patients daily and performing these
20 surgeries daily.

21 Q. Would you agree with me that Meng Chen is a
22 medical doctor?

23 A. Yes, I would.

24 Q. Okay. And do you have any knowledge one way
25 or another on how many TVT obturator devices Meng Chen

1 has implanted?

2 A. No, I do not have direct knowledge, no.

3 Q. Doctor, do you believe that the IFU for the
4 TVT obturator device should contain information on all
5 known risks?

6 A. No, I do not agree.

7 Q. Doctor, if Ethicon is getting reports in
8 post-market surveillance of permanent pain associated
9 with the TVT-O device, does the I -- does the TVT IFU
10 need to be updated to include that information?

11 A. No, it does not.

12 Q. Doctor, would you agree -- I just want to make
13 sure we're clear -- that the IFU for the TVT-O is a
14 source of information that a physician may rely on?

15 MR. KOOPMANN: Object to form. Asked and
16 answered.

17 THE WITNESS: Yes, it is a source.

18 BY MR. JACKSON:

19 Q. Okay. Doctor, if Ethicon were getting reports
20 of dyspareunia in post-market surveillance, do you
21 believe Ethicon had a right to update the IFU to include
22 that information?

23 A. Ethicon has a right to update and put any
24 information they so choose. But particularly with a
25 report of dyspareunia, I wouldn't feel that it was a

1 responsibility. As with any self-respecting pelvic
2 surgeon would know that operating in the pelvis carries
3 a risk of dyspareunia. And I would expect that Ethicon
4 would get multiple complaints of dyspareunia since this
5 is a pelvic surgery technique.

6 Q. Doctor, do you believe that Ethicon should
7 have included the risks of multiple revision surgeries
8 following the TVT-O procedure in the TVT-O IFU?

9 A. Once again, this is a risk that a surgeon
10 should understand when performing pelvic surgery. So,
11 yes, they have a right to put it in. I don't think they
12 had a responsibility to put it in.

13 Q. Doctor, is it your testimony that the risk of
14 multiple revision surgeries is a risk that's inherent
15 with any surgery?

16 A. Yes, it is.

17 Q. And that's common knowledge that any surgeon
18 would know?

19 A. Yes, it is. If I may state, particularly for
20 pelvic prolapse and incontinence, when you're actually
21 removing an organ the likelihood of needing to revise it
22 is small.

23 Q. Doctor, if I could ask you to turn to page 11
24 of your report.

25 A. Yes.

1 Q. Doctor, I'm sorry. Let's, instead, go to --
2 let's go to Page 15 of your report. I apologize.

3 A. 15?

4 Q. Yes, 15.

5 A. Yes.

6 Q. And, Doctor, I'm looking at a section called
7 "Plaintiffs' Theories are not Supported by the Published
8 Medical Literature or My Experience." Do you see that
9 section?

10 A. I do.

11 Q. And, Doctor, I'm looking at a sentence that's
12 about halfway down that paragraph that starts with, "The
13 excellent safety." Do you see that sentence?

14 A. Yes.

15 Q. And it says, "The excellent safety and
16 efficacy reported in the medical literature discussed
17 above, even after 17 years after the procedure, is
18 inconsistent with the idea that mesh is degrading in
19 vivo."

20 Did I read that correctly?

21 A. Yes, you did.

22 Q. And, Doctor, what -- what study are you
23 referring to when you say "17 years"?

24 A. The Cox study had information about that, yes.

25 Q. And, Doctor, is it your testimony that the Cox

1 study is the only 17-year study?

2 A. No. I should have this at my fingers, but,
3 honestly, it's just common knowledge that the TVTs have
4 published data regarding -- particularly the retropubic
5 data -- out to beyond 17 years, which specific study --
6 let me try to remember that. It was -- I should have
7 cited it.

8 Q. Does the Nielson study ring a bell as a study
9 that might have 17-year data?

10 A. Yes, that -- yes, it does.

11 Q. And just so we can wrap this up, Doctor, is it
12 your understanding that there's 17-year data for the
13 retropubic non-Exact TVT?

14 A. Correct.

15 Q. And, Doctor, for the TVT obturator device that
16 your report is in regards to, what is the longest term
17 study that you're aware of for the TVT obturator device?

18 A. Eleven years, I think.

19 Q. And do you know which study that is?

20 A. I did not cite them appropriately. No, I do
21 not remember.

22 Q. Okay.

23 A. But, again, the Cox study refers to both TVT
24 and TVT-O. I can take the time to find it.

25 Q. Doctor, is it your testimony that the mesh in

1 the TVT-O device does not curl, rope or fray after
2 implantation?

3 A. Yes, that is my testimony.

4 Q. And what is your basis for that opinion?

5 A. Well, in the few instances that I've seen it
6 in the body, and having made it to explant it, it was
7 not curled, roped or frayed. It continues to be
8 effective. And if it had roped, I would imagine it
9 would not be so. There's also, you know, published
10 tensile strength data on how it behaves under normal
11 circumstances.

12 Q. Doctor, if I could ask you to turn to page 18
13 of your report.

14 A. Certainly.

15 Q. And, Doctor, in the last paragraph on page 18
16 there's a sentence that says "In 2015," do you see that
17 sentence?

18 A. Yes.

19 Q. It says, "In 2015, Ethicon updated the adverse
20 reaction section of the TVT-O IFU to include some of
21 these risks."

22 Did I read that correctly?

23 A. Yes, you did.

24 Q. And, Doctor, what significance, if any, does
25 Ethicon's 2015 update to the TVT-O IFU have on your

1 opinions?

2 A. None. I don't feel that it was significant.

3 Q. And why don't you feel this IFU update was
4 significant?

5 A. Because they added additional risks that
6 should be known to pelvic surgeons, and pelvic surgeons
7 should be implanting this device.

8 Q. Doctor, on page 19 of your report, you include
9 a section on Ethicon's product brochures; is that
10 correct?

11 A. Yes.

12 Q. And, generally speaking, do you know whether
13 the TVT-O brochure always disclosed the risk of
14 dyspareunia?

15 A. I don't believe it did initially. I think it
16 does now, uh-huh.

17 Q. And, Doctor, have you read the TVT-O brochure
18 prior to implanting the TVT-O device in patients?

19 A. Yes.

20 Q. Okay. And, Doctor, have you also -- strike
21 that.

22 Doctor, have you provided a TVT-O brochure to
23 your patients for them to consider in evaluating whether
24 they'd like to have the TVT-O procedure?

25 A. Yes, I have.

1 Q. Doctor, do you believe you're an expert in
2 what sort of warning information should be included in a
3 product brochure such as the TVT-O brochure?

4 A. Yes, I use product brochures routinely,
5 uh-huh.

6 Q. Okay. Doctor, you cite a number of
7 meta-analyses in your report; is that correct?

8 A. That is correct.

9 Q. And, just generally, what is a meta-analysis?

10 A. It's a compilation of high-quality evidence,
11 generally randomized controlled trials, put together to
12 form conclusions based on larger numbers than a single
13 trial could provide.

14 Q. Okay.

15 A. If I may elaborate. They're not always
16 randomized controlled trials. However, they include not
17 established criteria for what they're going to include,
18 but based on generally established criteria and
19 specifically established criteria by the authors.

20 Q. Okay. And, Doctor, these meta-analyses, as
21 you said, contain information from multiple clinical
22 trials, correct?

23 A. That is correct.

24 Q. And so any given meta-analyses might have
25 information from many different products in it; is that

1 correct?

2 A. Yes, that is correct.

3 Q. Okay. So, for example, I believe you cite a
4 2014 meta-analyses by an author named Schimpf,
5 S-C-H-I-M-P-F --

6 A. Yes, I do, uh-huh.

7 Q. -- correct?

8 And does that 2014 meta-analyses contain
9 information on many different products beyond just
10 Ethicon products?

11 A. Yes, it does, uh-huh.

12 Q. Doctor, do you know what other sling products
13 are included in the studies in that meta-analysis?

14 A. I have it right here. Yeah, they included
15 Monarc, and Optrics, the Aris and SPARC.

16 Q. Doctor, those are all different mid-urethral
17 slings from different manufacturers other than Ethicon,
18 correct?

19 A. Yes, that's correct.

20 Q. And, Doctor, the Monarc sling you mentioned is
21 made by American Medical Systems; is that correct?

22 A. Yes.

23 Q. And I believe the Monarc sling is referred to
24 as a outside-in obturator approach; is that correct?

25 A. Yes, it is, uh-huh.

1 Q. And Ethicon's TVT obturator device is referred
2 to as an inside-out obturator device?

3 A. That is correct, yes.

4 Q. And so, Doctor, the Monarc and the TVT
5 obturator have slightly different surgical approaches to
6 them; is that fair?

7 A. Slightly different, yes, uh-huh.

8 Q. And, Doctor, how can you use data from other
9 products to support the safety of the TVT obturator
10 product?

11 A. It's essentially the same surgery. You're
12 comparing a -- an approach to a problem. So, you know,
13 an outside-in and an inside-out essentially performs the
14 same function as say, a Burch, but in a completely
15 different way. So a Burch is completely different than
16 a Monarc or a TVT-O. But a Monarc and a TVT-O enter the
17 same spaces. They're similar enough that they should be
18 considered together.

19 Q. Okay. Doctor, I know the Schimpf
20 meta-analyses and others, they rate the randomized
21 controlled trials that they include; is that correct?

22 A. Yes, that is correct.

23 Q. And they might give them a grade of A, B, C,
24 D, for example; is that correct?

25 A. Yes.

1 Q. And, Doctor, just generally, do you know how
2 one of these meta-analyses actually grades those
3 randomized controlled trials?

4 MR. KOOPMANN: Object to form.

5 THE WITNESS: It would take me some time to
6 specifically lay out exactly how they grade it, but they
7 grade it on data such as patient size, centers used,
8 numbers lost to follow up, data of that nature.

9 BY MR. JACKSON:

10 Q. Doctor, is that part of the methodology of how
11 a meta-analyses chooses which data to include?

12 A. It's part of the study design generally, yes,
13 uh-huh.

14 Q. And is that something you discuss in your
15 report?

16 A. For the specific literature I use. I mean, I
17 discuss meta-analysis as being a high-quality data, but
18 I don't discuss the specific methodology used in each --

19 Q. Okay.

20 A. -- in each report that I pulled -- report that
21 I pulled or used.

22 MR. JACKSON: I think that's all the questions
23 I have right now. I may have a few on follow-up after
24 you.

25 MR. KOOPMANN: Okay.

1 EXAMINATION

2 BY MR. KOOPMANN:

3 Q. Dr. Stanislaus, for the record my name is
4 Barry Koopmann. I'm representing Johnson & Johnson and
5 Ethicon in this case.

6 Do you practice evidence-based medicine?

7 A. Yes, I do.

8 Q. What is evidence-based medicine?

9 A. It's medicine based on literature analysis and
10 statistical analysis of the literature.

11 Q. Is some evidence thought of as being more
12 powerful than other evidence?

13 A. Yes.

14 MR. JACKSON: Objection. Form.

15 BY MR. KOOPMANN:

16 Q. What are the highest levels of evidence?

17 A. Meta-analysis and systematic reviews.

18 Q. And what is the lowest level of evidence?

19 MR. JACKSON: Objection. Form.

20 MR. KOOPMANN: What's the form objection?

21 MR. JACKSON: That it's very vague.

22 BY MR. KOOPMANN:

23 Q. Okay. Go ahead.

24 A. Observation, individual case reports.

25 Q. And where do level 1 studies fall within that

1 hierarchy of the different level of evidence within the
2 practice of evidence-based medicine?

3 A. High.

4 Q. And where do internal company documents, or
5 PowerPoint presentations, or emails, things like that,
6 fall on that hierarchy of evidence?

7 A. Very low.

8 Q. Does your TVT-O report that's marked as
9 Exhibit 1 contain your opinions regarding the safety and
10 efficacy of the TVT-O and the labeling for that device?

11 A. Yes, it does.

12 Q. And do you hold those opinions to a reasonable
13 degree of medical certainty?

14 A. Yes, I do.

15 Q. And are your opinions based, in part, on your
16 education, including your medical school, residency, and
17 continuing education?

18 A. Definitely, they are, uh-huh.

19 Q. Are your opinions also based on your clinical
20 training and experience?

21 A. Yes.

22 Q. Are your opinions also based on your review of
23 the peer-reviewed literature regarding the treatment of
24 incontinence?

25 A. Yes.

1 Q. Are your opinions also based on position
2 statements issued by the relevant organizations that
3 pertain to your specialty?

4 A. Yes, they are.

5 Q. Are your opinions also based on the -- any
6 conversations you have with colleagues that are
7 gynecologists or urologists treating incontinence in
8 women?

9 A. Yes, that does form the basis of my opinions.

10 Q. Are all of the opinions that you've expressed
11 here today given within a reasonable degree of medical
12 certainty?

13 A. Yes.

14 Q. Are the complications that you've seen in your
15 practice consistent with the warnings listed in the
16 adverse reaction section of the IFU for the TVT-O?

17 A. Consistent with if fewer than, but, yes,
18 consistently.

19 Q. Is it basic medical and surgical knowledge
20 that postsurgical pain can be chronic or temporary?

21 A. Yes, it is.

22 Q. Is it basic surgical knowledge that if pain
23 with intercourse presents itself after any SUI surgery
24 that that pain could be temporary or permanent?

25 A. Yes, that would be.

1 Q. Is it also basic surgical knowledge that when
2 an adverse reaction occurs, further surgery may be
3 required to correct that?

4 A. Yes, that is known.

5 Q. Even multiple surgeries?

6 A. Yes, even multiple surgeries.

7 Q. And that would be true for the Burch procedure
8 or pubovaginal sling procedures?

9 A. Yes, that would be true for both of those as
10 well. In fact -- yes, I've gone in multiple times on
11 pubovaginal sling procedures more so than I think I have
12 on the obturator.

13 Q. Do you have many patients who you have
14 implanted with the TVT-O to treat their stress urinary
15 incontinence who experience no complications in
16 connection with that surgery?

17 A. I'm sorry. Could you repeat that? Have I --

18 Q. Sure. Do you have many patients who you have
19 implanted with the TVT-O to treat their stress urinary
20 incontinence who have experienced no complications in
21 connection with that surgery?

22 MR. JACKSON: Objection. Form.

23 THE WITNESS: Yes, I have.

24 BY MR. KOOPMANN:

25 Q. And did you also have some patients who

1 experienced a complication?

2 A. Yes, I did.

3 Q. And when those patients experienced
4 complications, did you treat those complications?

5 A. I did.

6 Q. Before you ever used the TVT device or TVT-O
7 device back when you were in medical school, did you
8 learn about basic fundamental risks of any surgery?

9 A. Yes, I did.

10 Q. And did you also learn about basic fundamental
11 risks of any surgery during your residency?

12 A. Yes, of course, I did.

13 Q. And did you base your opinions regarding the
14 adequacy of the warnings in the TVT-O IFU on all of this
15 experience, education and training that we've discussed?

16 A. Absolutely, yes.

17 Q. Can you think of a single randomized
18 controlled trial that says that TVT-O mesh degraded or
19 was cytotoxic?

20 MR. JACKSON: Objection. Form.

21 THE WITNESS: No, I cannot.

22 BY MR. KOOPMANN:

23 Q. You've performed research in your career for
24 stress urinary incontinence as a part of your continuing
25 reading as a gynecologist and surgeon, correct?

1 MR. JACKSON: Objection. Form.

2 THE WITNESS: Yes, of course.

3 BY MR. KOOPMANN:

4 Q. Okay. And you testified earlier that you've
5 treated 150 patients, approximately, with a TVT-O; is
6 that right?

7 A. That is right.

8 Q. What has your experience been overall with the
9 device in the course of treating those patients?

10 A. My experience has been that the TVT-O device
11 is an extremely effective procedure for stress urinary
12 incontinence with a very, very low complication rate.

13 Q. Mr. Jackson asked you a question earlier today
14 about whether you had seen any documents indicating that
15 some Ethicon employee had said the Amid classification
16 is no longer valid. Do you remember that question?

17 A. I do remember that question.

18 Q. Just because one Ethicon employee says the
19 Amid classification is no longer valid, does that mean
20 the Amid classification is no longer valid?

21 A. No, it does not mean that.

22 Q. If one doctor, or a handful of doctors,
23 reported particle loss outside the context of a
24 scientific study that they thought was associated with
25 pain, what level of evidence would that be?

1 A. Again, that would be a very low level of
2 evidence. And I think I mentioned that earlier when
3 asked the question.

4 Q. Did you use Prolene suture before ever using
5 the TVT or TVT-O devices?

6 A. Yes, I did.

7 Q. Can you give any estimate of how many times
8 you think you've used Prolene suture in your career?

9 A. Many thousands.

10 Q. There were some questions earlier from
11 Plaintiffs' counsel about the wealth of peer-reviewed
12 data on the TVT. Do you remember those questions?

13 A. Yes.

14 Q. And that is the wealth of peer-reviewed data
15 that existed before you decided to start using it.

16 A. That's correct.

17 Q. Did that data also support your decision to
18 start using the TVT-O device?

19 A. Yes, of course.

20 Q. And why is that?

21 A. Because it's basically a modification of a
22 surgical technique. So knowing that the TVT was
23 effective and safe with extensive data allowed me to
24 consider an improvement in safety by performing the
25 TVT-O.

1 Q. One of the documents that you have included in
2 Exhibit 5 is a article by a lead author named Cox; is
3 that right?

4 A. Yes, uh-huh.

5 Q. Would you turn to that article, please.

6 A. Okay. Yes.

7 Q. If you will turn to the last page of that
8 article before the citations start. The last sentence
9 of that article in the conclusion section, what do the
10 authors say?

11 A. "Based on the literature a new gold standard
12 first-line surgical treatment for women with SUI is the
13 synthetic mid-urethral sling inserted through a
14 retropubic or transobturator approach."

15 Q. Even if studies do not specifically track
16 dyspareunia or other complications as a primary
17 endpoint, do the studies nonetheless comment on
18 complications such as dyspareunia?

19 A. Yes, they do.

20 Q. Would removing all of the sutures used during
21 a Burch procedure potentially require aggressive
22 dissection?

23 A. Definitely.

24 Q. Would removing everything that was implanted
25 during autologous fascial sling procedure or pubovaginal

1 sling procedure using a xenograft or allograft material
2 also potentially require aggressive dissection?

3 A. Absolutely.

4 Q. Are there other reasons that a mid-urethral
5 sling procedure using a polypropylene mesh wouldn't work
6 besides sling degradation?

7 A. Yes, yes.

8 Q. So just because a sling isn't working doesn't
9 mean the sling has degraded?

10 A. No. That is absolutely true.

11 Q. Would you agree that not all brands of meshes
12 are the same?

13 A. Yes, I would agree with that.

14 Q. In other words, Prolene is the product used in
15 the TVT family of slings, the mesh in those slings,
16 correct?

17 A. That is correct.

18 MR. JACKSON: Objection. Form.

19 BY MR. KOOPMANN:

20 Q. And Prolene is not used in other
21 manufacturers' mid-urethral slings, correct?

22 MR. JACKSON: Objection. Form.

23 THE WITNESS: Correct.

24 BY MR. KOOPMANN:

25 Q. Do you think it was necessary for Ethicon to

1 warn about not using the TVT-O procedure for patients
2 who are on anticoagulation therapy?

3 A. No, I do not think it was necessary.

4 Q. Okay. Why not?

5 A. Because one should not perform surgery on
6 patients that are anticoagulated. The bleeding risk is
7 too high.

8 Q. Do you think that a company has an obligation
9 to warn of a risk of using a product if that risk is
10 commonly known by licensed users of that device?

11 A. No, I don't think it's an obligation if it's
12 commonly known.

13 Q. One of the studies you have included in
14 Exhibit 5 is a study by Schimpf, and you were asked a
15 few questions about that a little bit ago. Would you,
16 please, pull it out.

17 A. Yes.

18 Q. In the first page of the Schimpf study, it
19 says that -- under the Study Design section it indicates
20 that the authors performed "a systematic review
21 including English-language randomized controlled trials
22 from 1990 through April 2013 with a minimum 12 months of
23 follow-up comparing a sling procedure for SUI to another
24 sling or Burch urethropexy"; is that right?

25 A. Yes.

1 Q. And that included many studies dealing with
2 the TVT-O device; is that correct?

3 A. Yes, it did.

4 Q. And those are listed in Table 1 of the study;
5 is that accurate?

6 A. That is accurate.

7 Q. And if you go to Table 3 of that study, one of
8 the complications that is tracked in this study for
9 various incontinence procedures is dyspareunia; is that
10 right?

11 A. That is right.

12 Q. What was the rate of the dyspareunia seen with
13 the transobturator mid-urethral slings studied in this
14 particular paper?

15 A. .16 percent.

16 Q. What was the rate with pubovaginal slings?

17 A. .99 percent.

18 Q. They also track the rate of exposure for
19 various incontinence procedures; is that right?

20 A. Yes.

21 Q. What was the rate of exposure in the studies
22 that were analyzed for purposes of the Schimpf study
23 with respect to obturator procedures?

24 A. 2.2 percent.

25 Q. And what was the rate of exposure for the

1 pubovaginal sling procedures?

2 A. 5.4 percent.

3 Q. And is this a study that you reviewed and
4 relied upon in forming your opinions regarding the
5 safety and efficacy of the TVT-O?

6 A. Yes, it is a study I relied upon.

7 Q. What level of evidence is this considered?

8 A. Level 1.

9 Q. Another study that you reviewed and relied
10 upon is the Ford, Cochrane review from 2015; is that
11 correct?

12 A. That is correct.

13 Q. That's a rather large study, is that
14 correct --

15 A. Yes.

16 Q. -- in terms of the volume of number of pages?

17 MR. JACKSON: Objection. Form.

18 THE WITNESS: Yes, it is.

19 BY MR. KOOPMANN:

20 Q. Okay. And you have a summary of that Cochrane
21 review in front of you; is that right?

22 A. That is right.

23 Q. I want to mark as the next exhibit an
24 excerpt -- excerpt from that study and ask you some
25 questions about those.

1 (Exhibit 11 was marked for
2 identification and attached hereto.)

3 BY MR. KOOPMANN:

4 Q. On the first page of the study where it's
5 below Abstract where it says "Selection Criteria" --

6 A. Okay.

7 Q. -- that indicates that the authors looked at
8 "randomized or quasi-randomized controlled trials
9 amongst women with SUI, USI or MUI, in which both trial
10 arms involve a MUS," or mid-urethral sling "operation";
11 is that right?

12 A. That is right.

13 Q. If you'll turn to the next page in the Main
14 Results section. They indicate at the top that they
15 included 81 trials in this study that evaluated 12,113
16 women; is that correct?

17 A. That is correct.

18 Q. Is this high level evidence, this Ford,
19 Cochrane review?

20 A. Yes, it is.

21 Q. Is it better evidence than a study involving
22 100-some patients?

23 A. Most definitely.

24 Q. Would it, in fact, include studies like Teo,
25 that we went over earlier, if that Teo study met the

1 inclusion criteria for this review?

2 A. Yes, it would.

3 Q. And in the authors' conclusions section on
4 that same page, it indicates "Mid-urethral sling
5 operations have been the most extensively researched
6 surgical treatment for stress urinary incontinence in
7 woman and have a good safety profile. Irrespective of
8 the routes traversed, they are highly effective in the
9 short and medium term, and accruing evidence
10 demonstrates their effectiveness in the long-term. This
11 review illustrates their positive impact on improving
12 the quality of life with women with SUI. With the
13 exception of groin pain, fewer adverse events occur with
14 the employment of a transobturator approach."

15 Did I read that correctly?

16 A. Yes, you did.

17 Q. And does this support your opinions regarding
18 the safety and efficacy of the TVT-O device?

19 A. Certainly, based on high quality data, yes.

20 Q. If you'll turn to the next page in this -- in
21 these excerpts. You should you see page 10.

22 A. Yes.

23 Q. In the right-hand column it indicates that,
24 "Type 1 meshes are macroporous monofilament meshes"; is
25 that right?

1 A. That's right.

2 Q. And what type of mesh is the TVT-O mesh?

3 A. Type 1.

4 Q. And it indicates below those bullet points
5 that, "Type 1 mesh has the highest biocompatibility with
6 the least propensity for infection"; is that right?

7 A. Yes, that's right.

8 Q. And about six or seven lines below that it
9 says, "Macroporous meshes (pore size in excess of 75
10 microns) easily allow macrophages, leukocytes,
11 fibroblasts, blood vessels and collagen to transverse
12 the pores; thus macroporous meshes promote tissue host
13 ingrowth with resultant biocompatibility and low risk of
14 infection"; is that right?

15 A. That is right.

16 Q. And in the next paragraph it says, "In
17 contrast, microporous meshes (pore size greater than 10
18 microns) allow bacteria to pass through and replicate,
19 but exclude macrophages"; is that right?

20 A. That is right.

21 Q. Then it says, "Multifilament tapes have
22 smaller pore sizes and are thus microporous"; is that
23 right?

24 A. That is right.

25 Q. Is the TVT-O mesh monofilament or is it

1 multifilment?

2 A. Monofilament.

3 THE VIDEOGRAPHER: Excuse me, Counsel. I need
4 to change the tape.

5 MR. KOOPMANN: Okay.

6 THE VIDEOGRAPHER: This marks the end of Disk
7 2, Volume I, in the videotaped deposition of Dr. Mareeni
8 Stanislaus. The time on the monitor is 4:43 p.m., and
9 we are now off the record.

10 (Recess.)

11 THE VIDEOGRAPHER: We're back on the record.
12 This marks the beginning of Disk 3, Volume I, in the
13 videotaped deposition of Dr. Mareeni Stanislaus. The
14 time on the monitor is 4:48 p.m.

15 You may continue.

16 BY MR. KOOPMANN:

17 Q. Doctor, do you have page 28 of the Ford,
18 Cochrane review excerpts in front of you?

19 A. Yes, I do.

20 Q. On page 28 it discusses the types and rate of
21 pain seen with transobturator versus retropubic
22 procedures; is that right?

23 A. That's correct.

24 Q. And it indicates in the right-hand column
25 that, "Both groin and suprapubic pain occurrence were

1 short-lasting, with most resolving within the first six
2 months"; is that right?

3 A. That is right.

4 Q. And then if you'll turn to page 30 of
5 Exhibit 11, please. There's a section there discussing
6 "Sexual Function Quality of Life Measures"; is that
7 right?

8 A. That is right.

9 Q. And at the bottom of the left-hand column it
10 says, "In all the trials there was significant
11 improvement in sexual function from baseline scores
12 during the follow-up period that spanned 6 to 24 months.
13 There were no significant differences between the
14 groups." Is that right?

15 A. That is right.

16 Q. And the two groups being retropubic slings and
17 obturator slings?

18 A. Yes.

19 Q. It then says, "A 24-month follow-up, rates of
20 superficial and deep dyspareunia were low, with no
21 difference between the groups."

22 Did I read that correctly?

23 A. Yes, you did.

24 Q. And does that information support your
25 opinions regarding the safety and efficacy of the TVT-O

1 device?

2 A. Definitely, yes.

3 Q. I think one of the documents that you brought
4 along today is the AUGS SUFU updated physician
5 statement.

6 A. Yes.

7 Q. And you also have a statement by Douglas Hale,
8 M.D., on June 23rd, 2016 pertaining to that statement?

9 A. No.

10 MR. KOOPMANN: Let's mark a copy of that
11 Douglas Hale statement as Exhibit 12, please.

12 (Exhibit 12 was marked for
13 identification and attached hereto.)

14 MR. JACKSON: Counsel, do you have one for me?

15 MR. KOOPMANN: Just one second.

16 BY MR. KOOPMANN:

17 Q. Dr. Stanislaus, would you take a moment to
18 review that, please.

19 (Pause while witness peruses document.)

20 BY MR. KOOPMANN:

21 Q. Having read this statement we've marked as
22 Exhibit 13, does this refresh your recollection that you
23 have seen this statement in the last few weeks or --

24 A. Oh, yes, yes.

25 Q. Okay. And this is a statement that

1 accompanied a recent update to the AUGS SUFU position
2 statement?

3 A. Yes.

4 Q. And the AUGS SUFU position statement on mesh
5 mid-urethral slings for stress urinary incontinence is
6 something that you -- well, it's something that was
7 first published back in 2014, I think; is that right?

8 A. That's correct, yes.

9 Q. And that's a document that you've reviewed,
10 and relied upon, and cited and discussed in your TVT-O
11 general report; is that correct?

12 A. That is correct.

13 Q. And was this AUGS SUFU position statement
14 recently updated?

15 A. Yes.

16 Q. And that was after you issued your TVT-O
17 general report in this case?

18 A. Correct, it was.

19 Q. Is the updated AUGS SUFU position statement
20 also consistent with your opinions regarding the safety
21 and efficacy of the TVT-O device?

22 A. Absolutely, yes.

23 Q. And the -- one of the things that Dr. Hale
24 notes in Exhibit 12 is that he was happy to announce
25 that the societies contacted by AUGS undertook their own

1 thorough review of this document and responded with
2 overwhelming support; is that correct?

3 A. That is correct.

4 Q. And he was indicating that he could now say
5 that, in addition to AUGS and SUFU, other organizations
6 supporting our position statement include A-C-O-G, or
7 ACOG, SGS, AAGL, and AUA; is that correct?

8 A. That is correct.

9 Q. He went on to say, "Likewise, patient advocacy
10 groups, including NAFC and WHF, also added their support
11 of the document." Is that correct?

12 A. That is correct.

13 Q. And the AAGL is the American Association of
14 Gynecological Laparoscopists; is that correct?

15 A. Yes.

16 Q. And I think you indicated earlier you're a
17 member of AUGS?

18 A. I am.

19 Q. The American Urogynecological Society?

20 A. Yes.

21 Q. Another organization that supports this
22 statement is the American College of Obstetricians and
23 Gynecologists?

24 A. Yes.

25 Q. Are you a member of that?

1 A. I am.

2 Q. Another organization that supports this
3 statement is the National Association for Continence; is
4 that correct?

5 A. That is correct.

6 Q. And in the updated AUGS SUFU statement that
7 you have in front of you, that indicates on the third
8 page that the National Association for Continence is the
9 national private nonprofit 501(c)(3) organization
10 dedicated to improving the quality of life of people
11 with incontinence, voiding dysfunction, and related
12 pelvic disorders; is that correct?

13 A. That is correct.

14 Q. SGS is the Society of Gynecologic Surgeons; is
15 that right?

16 A. That is right.

17 Q. And they're a supporting organization of this
18 statement?

19 A. Yes.

20 Q. And, finally, the Womens Health Foundation is
21 a supporting organization of this statement; is that
22 correct?

23 A. That is correct.

24 Q. And that is a nonprofit organization dedicated
25 to improving the pelvic health and wellness of women and

1 girls throughout -- I'm sorry -- through community based
2 programs and services research and events; is that
3 correct?

4 A. That is correct.

5 MR. KOOPMANN: Madam Court Reporter, could you
6 please mark this exhibit as Exhibit 14. I'm sorry.
7 Before we that, then, could we mark the AUGS SUFU
8 statement as Exhibit 13?

9 (Exhibit 13 was marked for
10 identification and attached hereto.)

11 MR. JACKSON: That's the updated AUGS SUFU
12 statement, correct?

13 (Reporter clarification.)

14 MR. KOOPMANN: And counsel just corrected me.

15 Q. But Exhibit 13 is the updated AUGS SUFU
16 position statement, correct?

17 A. Correct.

18 MR. KOOPMANN: Thank you, Counsel.

19 (Exhibit 14 was marked for
20 identification and attached hereto.)

21 BY MR. KOOPMANN:

22 Q. Do you have Exhibit 14 is front of you,
23 Dr. Stanislaus?

24 A. I do.

25 Q. And is this an abstract of a couple articles

1 that has just been published since you issued your TVT-O
2 general report?

3 A. Yes.

4 Q. And the abstract on the second page is
5 entitled, "The Myth: In Vivo Degradation of
6 Polypropylene meshes" by Ong, White and Thames. Is that
7 correct?

8 A. Yes.

9 Q. And you've had a chance to review this
10 published abstract since issuing your TVT-O general
11 report?

12 A. Yes, I have.

13 Q. And what was the conclusion of the authors in
14 that particular abstract?

15 A. They concluded that Prolene meshes did not
16 undergo meaningful or harmful degradation in vivo.

17 Q. Does this abstract support your opinion that
18 the -- that clinically significant degradation of the
19 TVT-O does not occur?

20 A. Yes, it does.

21 Q. You were asked questions by Plaintiffs'
22 counsel earlier about Exhibit 10, which was an email
23 chain, including a couple emails from Dr. Meng Chen.

24 A. Yes.

25 Q. Do you recall those questions?

1 A. Yes.

2 Q. Okay. And you were asked about Ms. Chen's --
3 or Dr. Chen's statement that from what she sees each day
4 these patient experiences are not transitory at all. Do
5 you remember that?

6 A. I do remember that.

7 Q. Does the TVT-O IFU say that patient
8 experiences of extrusion and erosion, fistula formation
9 or inflammation are transitory?

10 A. No.

11 Q. The Nilson study that was referenced earlier,
12 that had 17-year data on the TVT --

13 A. Yes.

14 Q. -- sling, that TVT sling use the same mesh as
15 what's used in the TVT-O; is that your understanding?

16 A. That is my understanding, yes.

17 Q. And you cited that TV -- that Nilson study in
18 your report?

19 A. I did.

20 Q. Do you have a study by a Dr. Athanasio in
21 your Exhibit 5.

22 A. Yes.

23 Q. And that study has seven years' data on the
24 TVT-O; is that correct?

25 A. That is correct.

1 Q. You were asked some questions earlier about
2 the TVT family of products brochures and whether they
3 contained -- they all contained a warning of a risk of
4 dyspareunia. Do you remember those questions?

5 A. I do.

6 Q. Did you counsel your patients about a risk of
7 dyspareunia even before you saw that in a TVT-O
8 brochure?

9 A. Yes, I did.

10 Q. How did you know to do that?

11 A. As a pelvic surgeon, I know to counsel my
12 patients regarding dyspareunia because of my education
13 and training.

14 Q. You were asked some questions earlier about
15 the Teo study that was marked Exhibit 9. Do you have
16 that in front of you?

17 A. Yes.

18 Q. And this was a study that included a total of
19 127 women who were recruited for this study; is that
20 right?

21 A. That is right.

22 Q. If you'll turn to the second page, which is
23 actually numbered 1351 in the Journal.

24 A. Uh-huh.

25 Q. Do you see that page?

1 A. I do.

2 Q. The bottom of the right-hand column in the
3 Results section, in the second paragraph there, it says,
4 "During recruitment a few studies were published showing
5 similar curates for the 2 procedures but a high
6 incidence of leg pain in patients after receiving a
7 transobturator tape. After discussing these data at an
8 investigator meeting we decided to stop recruitment
9 before the full calculated sample was recruited since it
10 was deemed that clinical equipoise had been lost."

11 Is that correct?

12 A. That is correct.

13 Q. What is higher level evidence, the Teo study
14 or symptomatic reviews in meta-analyses like the
15 Schimpf, Ford, Tommaselli and Ogah systematic reviews
16 that you cited in your TVT-O general report?

17 A. Of course the systematic reviews and the
18 meta-analyses cited.

19 Q. And, in fact, do studies like the Schimpf,
20 Ford and Tommaselli and Ogah papers, the systematic
21 reviews and meta-analyses, and Cochrane reviews, take
22 into account studies like Teo in the course of their
23 systematic review and analysis of the literature?

24 MR. JACKSON: Objection. Asked and answered.

25 THE WITNESS: Yes, they do. In fact, it says

1 data on women already recruited would be a value in
2 future systematic reviews in metanalysis in that paper.

3 BY MR. KOOPMANN:

4 Q. You also cited some registry studies that
5 discuss very large numbers of patients --

6 A. Yes.

7 Q. -- is that correct?

8 A. That is correct.

9 Q. And you've cited those and discussed them in
10 your TVT-O general report?

11 A. I have.

12 Q. One of those studies is a study by a Dr. Unger
13 and colleagues?

14 A. Oh, yes, uh-huh.

15 Q. Do you have that study in front of you in
16 Exhibit 5 or in -- or separately?

17 A. I have it in Exhibit 5.

18 Q. Do you have that in front of you now?

19 A. Yes.

20 Q. The Unger study was a case controlled study of
21 3,307 patients receiving a mid-urethral sling over a
22 10-year period to analyze indications and risk factors
23 necessitating revision surgery; is that right?

24 A. That's right.

25 Q. And the revision rate -- strike that.

1 The revision rate was 2.7 percent for
2 retropubic and transobturator slings over that 10-year
3 period; is that right?

4 A. That's what they reported, yes.

5 Q. And the mesh erosion rate was 21.3 percent of
6 those 2.7 percent; is that correct?

7 A. Yes.

8 Q. And the vaginal pain or dyspareunia revision
9 rate, in other words, the rate at which women had to
10 have a sling revision due to vaginal pain or
11 dyspareunia, was 7.9 percent of the 2.7 percent,
12 correct?

13 A. That is correct.

14 Q. And another study that you reviewed and relied
15 on in forming your opinions was the Jonsson Funk
16 registry study from 2013; is that correct?

17 A. That is correct.

18 Q. And that study involved an analysis of a
19 population-based cohort of 188,454 commercially insured
20 women who underwent a sling procedure between 2001 and
21 2010; is that right?

22 A. Yes.

23 Q. In the nine-year cumulative risk of sling
24 revision removal in that patient population of 188,454
25 women was 3.7 percent; is that right?

1 A. Absolutely, uh-huh.

2 Q. You also reviewed and relied on and cited in
3 your TVT-O general report a study by a Dr. Welk --

4 A. Yes.

5 Q. -- in 2015; is that correct?

6 A. Yes.

7 Q. Would you, please, pull up that study?

8 A. Okay.

9 Q. This was a population-based retrospective
10 cohort study of all adult women undergoing synthetic
11 mesh surgery for SUI in Ontario, Canada from April 1st,
12 2002 through December 31st, 2012, right?

13 A. That's right.

14 Q. And that included 59,878 women; is that right?

15 A. That is right.

16 Q. And complications were treated in 1,307 of
17 those 59,887 women; is that correct?

18 A. That's correct.

19 Q. And that's a 2.2 percent complication rate; is
20 that right?

21 A. Yes.

22 Q. And the 10-year cumulative incidence of
23 complications was 3.29 percent; is that correct?

24 A. Yes.

25 Q. And that's a study that supports your opinions

1 regarding the safety and efficacy of the TVT-O device?

2 A. Yes, definitely.

3 MR. KOOPMANN: Those are all the questions I
4 have for you. Thank you, Dr. Stanislaus.

5 MR. JACKSON: I have a few follow up.

6 Counsel, can I get a copy of Exhibit 13? I
7 didn't get it.

8 MR. KOOPMANN: Yes. Which is that?

9 THE WITNESS: That's the updated physician
10 statement.

11 MR. KOOPMANN: So that -- that copy was just
12 included in her materials. I don't know if I have an
13 identical copy to that, but I have --

14 MR. JACKSON: Could we just go off the record
15 for a second?

16 THE VIDEOGRAPHER: The time on the monitor is
17 5:05 p.m. We're going off the record.

18 (Off the record discussion.)

19 THE VIDEOGRAPHER: Going back on the record.
20 The time on the monitor is 5:06 p.m.

21

22 FURTHER EXAMINATION

23 BY MR. JACKSON:

24 Q. Doctor, could I ask you to take out
25 Exhibit 14, which is marked as Exhibit 14.

1 A. Yes.

2 Q. And you were just asked some questions by
3 counsel about a study on the second page of this
4 Exhibit 14; is that correct?

5 A. That is correct.

6 Q. And the title of that study is "The myth: In
7 Vivo Degradation of Polypropylene Meshes"; is that
8 correct?

9 A. Yes.

10 Q. Are you familiar with any of the authors of
11 this study?

12 A. No.

13 Q. Are you aware that Dr. Thames is currently a
14 expert for Ethicon in this litigation?

15 A. I am, yes.

16 Q. Okay. And, Doctor, this study that you were
17 just asked about, what level of evidence is this?

18 A. It's basic science evidence, but low level in
19 terms of the randomized controlled trial level.

20 Q. So it's not level 1 evidence?

21 A. No, it is not level 1 evidence.

22 Q. Doctor, you were asked some questions about an
23 Exhibit 13, which is a AUGS SUFU position statement
24 update that has come out since your expert report in
25 this case; is that correct?

1 A. That is correct.

2 Q. And, Doctor, on the first and second pages of
3 this document there's something that says,
4 "Justification for the Position Statement"; is that
5 correct?

6 A. Yes.

7 Q. And one of the things that's a justification
8 for this position statement is that the FDA has clearly
9 stated that polypropylene mid-urethral slings is safe
10 and effective for the treatment of SUI; is that correct?

11 A. Yes, that's correct.

12 Q. So, Doctor, is the fact that the FDA has
13 spoken on the safety of mid-urethral slings important to
14 your opinions in this case?

15 MR. KOOPMANN: Object to form.

16 THE WITNESS: It is important insofar as it
17 forms the basis for this justification, yes.

18 BY MR. JACKSON:

19 Q. Okay. Doctor, do you believe you could offer
20 the same opinions in this case without making reference
21 to AUGS or the FDA?

22 A. Yes.

23 Q. Doctor, do you believe statements made by AUGS
24 and the FDA are strong evidence that support your
25 opinions in this case?

1 A. I do.

2 Q. And would you like to be able to talk about
3 statements made by AUGS and the FDA at trial?

4 A. Yes, I would.

5 Q. Doctor, when counsel was asking you some
6 questions a few moments ago, I believe you stated that
7 you've implanted many thousand Prolene sutures in your
8 career; is that correct?

9 A. That's correct.

10 Q. Okay. And aside from the Burch procedure,
11 what indications have you implanted Prolene sutures for?

12 A. Oh, for sacrospinous ligament fixation,
13 multiple vaginal vault suspension procedures,
14 paravaginal defect repairs. Oh, Prolene. Probably used
15 some in repair of abdominal fascia. And, sorry, I did
16 use some on the razin prorare procedures. We used
17 Prolene then.

18 Q. Okay. Is that it?

19 A. There may be others, but those are the
20 principal ones, yes.

21 Q. Doctor, do you know when the Tommaselli study
22 was published?

23 A. I have to look that up. I think it was 2013.

24 Let me --

25 Q. Doctor --

1 A. 2015. Yes, 2015.

2 MR. KOOPMANN: Counsel, your time's up.

3 MR. JACKSON: Okay. I have no more questions.

4 THE WITNESS: Okay.

5 THE VIDEOGRAPHER: One moment, please.

6 This marks the end of Disk 3, Volume I, in the
7 videotaped deposition of Dr. Stanislaus. The time on
8 the monitor is 5:12 p.m., and we are now off the record.

9 THE REPORTER: Did you want a copy of this?

10 MR. KOOPMANN: We have a standing order with
11 Golkow.

12 (At the time of 5:12 p.m. the deposition
13 was concluded.)

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PENALTY OF PERJURY CERTIFICATE

I, MAREENI STANISLAUS, M.D., hereby declare I am the witness in the within matter, that I have read the foregoing transcript and know the contents thereof; that I declare that the same is true to my knowledge, except as to the matters which are therein stated upon my information or belief, and as to those matters, I believe them to be true.

I declare being aware of the penalties of perjury, that the foregoing answers are true and correct.

Executed on the _____ day of _____,
20____, at _____, _____.
(CITY) (STATE)

MAREENI STANISLAUS, M.D.

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1 CERTIFICATE OF REPORTER

2 I, ASHALA TYLOR, CSR No. 2436, in and for the State
3 of California, do hereby certify:

4 That the foregoing proceedings were taken before me
5 at the time and place herein set forth; that any
6 witnesses in the foregoing proceedings, prior to
7 testifying, were placed under oath; that a verbatim
8 record of the proceedings were made by me using machine
9 shorthand which was thereafter transcribed under my
10 direction; further that the foregoing is an accurate
11 transcription thereof.

12 That before the completion of the deposition, review
13 of the transcript was not requested.

14 I further certify that I am neither financially
15 interested in this action nor a relative or employee of
16 any attorney or any of the parties hereto.

17 In compliance with Section 8016 of the Business and
18 Professions Code, I certify under penalty of perjury
19 that I am a Certified Shorthand Reporter with California
20 License No. 2436 in full force and effect.

21 WITNESS my hand this 21st day of July, 2016.

22

23

24 _____
Ashala Tylor, CSR #2436, RPR, CRR, CLR

25